Department Of Health And Human Services

Substance Abuse And Mental Health Services Administration Drug Testing

Advisory Board

Scientific Meeting On:

Drug Testing Of Alternative Specimens And Technologies

Day Three

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P R O C E E D I N G S (8:30 a.m.)

Agenda Item: Public Comments

DR. AUTRY: Before we get started in this morning's agenda, let me just say that the board met for a few minutes last night and again this morning to try and

figure out when our next meeting was going to be. Although we don't have the hotel or the absolute dates, it looks like it is going to be the first week in August. So if you want to put a tentative hold on that, we'll try to come back to you later on this morning and talk to our logistics people, and see if we can get the actual dates and places where we will be at that.

As you know, this whole meeting has been open, and it has been open for the public on purpose, because we wanted to have as much input into the deliberative processes of the board as we looked at all the technologies and matrices that are currently available for work place testing. The next meeting will also be open to the public.

As part of the process for this meeting, we set

aside time this morning for people to sign up and to comment on anything that they wanted to with reference to the proceedings so far, with information that would help the board, with questions for presenters who

have presented so far, and for any other general information that you wanted to bring to the board's attention for their deliberations later on this summer.

We have a total of 16 people who have signed up. What I am going to propose that we do this morning is have all of the commenters go ahead and make their comments. Get all 15 or 16 of them on the table, and then after everybody has presented, then have time for questions and answers. So with your indulgence, I think that will be a smoother way to go this morning, otherwise we will end up with some people who have 5 minutes of presentation, which everybody is limited to, and then 15 minutes of questions, and we'll never get through all 16 people.

The game plan is that everybody is limited to five minutes this morning in terms of their public comments. If there are specific questions that you want to ask the board, because this is being transcribed, those will be a matter of public record, and we will feed those into them for their deliberations later on this summer. I don't think we are going to have time for the board to be able to enter into a dialogue. This is primarily to get information to the board at this point in time, but we will try and make sure that we address all of those.

We will all try and keep sort of a running list of questions that have come up for presenters, but I am going to encourage all of the presenters to listen for their own questions. I can assure you that when I am chairing a meeting, I don't catch everything that goes. I would appreciate everybody sort of feeding in and helping us.

Again, this is primarily to elicit further

comments or clarifying issues for the board and for the presenters. I will be the timekeeper I assume this morning.

Since Donna has not lent me her whip, I will probably be a little easier than she was, but I will try and keep people to five minutes.

We agreed that we would go in the order in which

people have signed up. If I mispronounce somebody's name, I apologize. It's because I'm not doing a very good job of reading your handwriting. As a physician, I know it is unusual for have one of us complain about other people's handwriting, but I will do the best I can.

The first commenter is James Fitzsimons.

MR. FITZSIMONS: Good morning. Initially I would like to thank you for the opportunity to attend this conference. It has been very educative.

I have had most of my questions answered. People generously gave of their time during breaks and that type of thing, but with all the discussions relative to quality control, to the reliability and sensitivity of the testing, the integrity of the samples, that type of thing, I have one

nagging question, and I think this is the ideal forum to address it.

As we are all aware, many laboratories commonly

use reagent extenders. I know that I have seen a letter from Barien(?) Diagnostics indicating that. When someone dilutes their reagents, they will not guarantee their accuracy. I think this was sufficiently important that in the last Federal Bureau of Prisons RFP that I reviewed they modified it to indicate that you must follow the reagent manufacturer's instructions.

My question therefore is that if a laboratory is

in fact using extenders, are they truly doing an emit screen? By definition is that an admit screen? As a long time professional in the criminal justice system, my concern is that we routinely see people lose their freedom because of an emit positive, and I shudder at the thought of defense counsels getting this concept clearly in mind, that we are saying this person gave a positive test by emit, and was it truly an emit test?

My second question has to do with the federal

guidelines, which I believe imply that an amino assay test must be FDA approved. Is my question -- is that implied, or is that required?

Third and finally, my belief is that if in fact we are allowing this to transpire, that the consumer should be informed that the laboratory is not following the reagent manufacturers' instructions; that is not, conceivably, an FDA approved process.

Thank you very much.

DR. AUTRY: Thank you. Mr. Fitzsimons, I was

remiss in not asking, when people come up, please identify yourself and whatever affiliations you have also.

MR. FITZSIMONS: My name is James Fitzsimons. I

was a criminal justice professional for 30 years. I then went to work at a laboratory, and most recently have been involved as a consultant in the private sector.

DR. AUTRY: Thank you. Well, you have set a good tone for the rest of us.

Next is Julie Murdoch.

MS. MURDOCH: I will apologize in advance. We

have some very good speakers in the last couple of days. I'm going to have to read mine, because I just wrote it last night.

Good morning. My name is Julie Murdoch, and I am the Director of DOT Testing Programs and Senior Associate for Bensinger, DuPont & Associates. My history -- as many of you in the audience may know -- I was with the Department of Army for a number, and then with the Federal Aviation Administration. In fact, there are some here in the room whose laboratories I inspected, and who may fondly remember me as the Attila the Nun.

Before I begin my comments, I would like to

comment the Drug Testing Advisory Board for this meeting. I commend you not only for a successful meeting, but also for what these past two days represent, that is, your willingness to be open to the possibility of change, tempered by a healthy understanding that a cautious approach is the only sensible one to take in deciding whether to embrace those changes.

That said, let me turn to my comments. I have a

few general comments, and then some specific comments in response to the presentations we have heard this week.

As an overarching comment, I would urge the board, as it deliberates on these presentations, to keep in mind what I believe to be a fundamental consideration that cannot be lost amid the plethora of exciting new technologies and the flood of research. That is that a variety of constituencies are going to be affected by any changes that are ultimately adopted by the Department of Health and Human Services.

These include not only manufacturers and laboratories, but also of course: the employers; employees; the general public; the enforcement personnel responsible for enforcing these rules; and others. As we all know, the needs and interests of these various groups are not always consistent, and as is always the case, a balance will have to be drawn.

For example, I think that several speakers touched on this balancing act when discussing the revision to the opiate levels. Even in an arena where the scientific literature appears to be fairly well settled, the conflict between the employee's rights, the employer's need to reduce costs, the desire to maximize detection, and the laboratory's interest in efficient testing all serve to complicate what is a seemingly straightforward scientific issue. These same types of conflicts are likely to occur, and concomitant balances will have to be drawn in virtually every area under consideration in this meeting.

Second, I urge the board to look with a great deal of care at issues of variability. Clearly, one of the reasons for the success of the urine drug testing program has been its uniformity. As a non-scientist I can't speak to the possible variations that must be controlled in urine drug testing, however, I can speak as an attorney, and as one who spent a great deal of time explaining drug and alcohol testing methodologies to an even less educated populace.

It is one of the great strengths of the current testing procedures and protocols that in general results can be reproduced across laboratories and industries, and everyone is seemingly treated the same.

It is my opinion that unless a testing system can

be implemented in terms of collection, analysis and results with a high degree of uniformity and a minimum of subjective intervention, the system does not belong in a federally mandated work place program affecting millions of lives. This is not to say that a limited application of variable systems would not be appropriate, but the HHS and the other federal regulators must regulate for the masses.

My next general comment is to endorse

wholeheartedly the presenters who have expressed the opinion that training must be a critical component in the adoption of any new methodologies or matrices. I'm sure many of us remember thinking in the early days of these programs, how hard can it be for the collector to get some a urine in a bottle, seal it, fill out a piece of paper and ship it to the laboratory? Of course the answer is it isn't hard to do it, but it is hard to do it consistently and completely

right.

Untrained or poorly trained collection personnel have been and remain the bane of the forensic drug testing program, however it is not just collector training that should be a consideration. In addition, I believe that education of affected managers, employees, labor organizations and others directly implicated by the programs is critical.

An experience I'm sure many in this audience share is trying to convince a skeptical decision-maker or employee of the accuracy and security of the drug and alcohol testing methodologies. I believe that the board could forestall the recurrence of many of these problems we saw in the early years of the programs by including an educational component in the requirements for any new methodology or matrix.

Before I hear outraged cries about the cost of

such a component, please note that I am not necessarily saying that it must be face-to-face training. As a suggestion, perhaps manufacturers or laboratories could be required to produce education materials comprehensible to someone other than a toxicologist or an FDA analyst a condition of consideration in the federal program.

I also think that training for medical review

officers will become even more critical if changes are adopted. I believe that the lack of uniform training for MROs, especially with respect to regulatory or non-clinical aspects of their duties is a significant weakness in the current system, and the addition of other matrices or

technologies will only exacerbate that weakness if the way MROs are trained does not improve.

I can submit the rest in writing?

DR. AUTRY: Again, anything that you don't get on the record, by all means do submit it in writing. In fact, at the end of the public comment period this morning, we have a series of comments or questions that people who have left, have left with us, and we will read those into the record to make sure everybody has a fair shot at that.

Thank you, Ms. Murdoch. Next is Harb Hayre.

DR. HAYRE: First, I must confess that my background was not helpful in figuring out what the new technologies were. Anyway, I have spent my life as a professor, and I am with the Chemical Fitness Monitoring Company in Houston, Texas.

First, I want to congratulate SAMHSA and NIDA and the drug testing industry for bringing the classical test tube chemical analysis technology to new heights.

Secondly, SAMHSA's assistant administrator, Mr.

Paul Schwab, in his opening comments expressed the hope that one day we will develop a non-invasive technology, and I think that is indeed praiseworthy.

Alternative specimens and technologies are still limited to body fluids and hair. I saw a graph or a chart in one of the presentations. It contained nothing but the fluids. There are many other outputs from the body which can be monitored, and they should be included in the overall regimen.

Second, all these body fluids -- you have done indeed a fantastic job in chemical detection of particular chemicals associated with drugs. Yet I don't see a chemical fitness criteria established along with it, because we keep changing the levels or thresholds.

SAMHSA has almost perfected the rules -- I said almost, because we keep changing -- for nanogram versus deciliter technology, with remaining and continuing concerns for adulteration, dilution, false negatives and false positives, chain of custody, threshold settings, drug

interaction, pharmaceutical and poppy seed concerns, and individual tolerance levels. I think that I did not see in any of the comments or presentations.

Our multi-chemical using and pill munching society indeed offers the challenge to our drug regulations in that a subject may turn out to be negative in all six drugs and alcohol, and yet be impaired. For example, the police are complaining that 15 percent of their bookings turn out to

be negative, and yet they can't walk the line, and the nystagmus is positive. So the industry has a challenge and so has the SAMHSA.

Finally, it is sincerely hoped that we consider

ways to include newer technologies. I would not want to detail all of them. I would say electronics and body signal analysis technologies -- and there are lots of them. I hope SAMHSA would widen their vision and scope in considering these.

Thank you very much.

DR. AUTRY: Thank you. Next is David Blank.

DR. BLANK: Good morning. I am Dr. David Blank.

I am the Drug Detection and Deterrence Branch Head for the Department of the Navy. My office sets the drug testing policy for 400,000 members of the Navy, and overseas drug testing for both the Navy and Marine Corps. We conduct about 1 million urinalysis per year, and will shortly be conducting pre-employment testing for an additional 110,000 potential Navy recruits.

I would like to take this opportunity to tell you

a short story, read you a brief letter, and then ask a simple question. I have been with the Navy's drug program for 14 years. My first task upon joining this program was to respond to a letter addressed to the Secretary of the Navy from a guy named Dr. Werner Baumgartner from the Veterans Administration, who claimed to have a test that had lots of advantages over urinalysis.

Coming from a research environment, I first proceeded to gather all the papers on hair analysis that were published. I arrived at my office one morning and proceeded to read all the papers that existed on hair analysis for drugs of abuse. I finished reading these papers, then went to lunch -- and I'm a slow reader. Things do indeed change.

To make a long story short, after many discussions and visits to see Dr. Baumgartner, one day he and I finally found ourselves sitting on a park bench at the Veterans Administration Hospital, where we hammered out the outline and contract for the first clinical trials of hair analysis.

The Navy furnished some funds for supplies and opened the doors of its drug treatment facility to Werner. Sample collection commenced.

Neither Werner nor I ever published those results, but I can now tell you that while they were promising, they were far from conclusive. At that point, Werner decided to form Psychemedics and the Navy decided to continue to pursue exploring hair analysis as a possible adjunct to urinalysis.

I'm telling you this story because I want you to

know that the Navy has had a longstanding interest in trying to understand and improve hair analysis techniques. I contacted Dr. David Kidwell from the Naval Research Laboratory to help in evaluating hair analysis. Dr. Kidwell and I decided to cut to the chase, and concentrate our research efforts on one topic, contamination of hair via passive exposure.

One guiding principle of the Navy's program both then and now is that the Navy should not terminate the career of a sailor because of a false positive. If you

haven't read our papers on the passive exposure issue, you will find them in any of the compendiums of hair analysis research publications or elsewhere.

I will summarize all of these data by saying that contamination of hair by passive exposure to drugs of abuse happens. This is not a scientific theory, but a scientific fact. I still consider myself a scientist, and I do not use these words lightly.

We observed this in sample after sample, study

after study. Once drugs are passively incorporated into hair, they behave as if they were deposited via injection, and cannot be removed by the washing procedures described here. If you do not believe passive exposure is a problem, I urge you to read these studies and replicate our simple procedures and see for yourself.

Kidwell and Smith have further shown that contamination of hair due to passive exposure of drugs of abuse occurs in natural populations.

Now as a result of dozens of papers in this area, Dr. Kidwell has achieved some notoriety as an expert in passive exposure and receives letters from people out there.

Dr. Kidwell is actually sorry he could not be here to read this himself, but he suffered a serious fracture on Sunday and is out of commission for a while.

Now we have heard of the mythical Bubba. We have heard about the two applicants at the truck depot. Here is a letter from a real person. This is just a representative letter. We get these letters all the time, and the subject could just as easily have been racial bias.

"Dear Dr. Kidwell, I am a police officer. I am currently researching the validity of hair analysis for drugs of abuse and have acquired some manuscripts written by you and some of your colleagues. I am writing to ask for your assistance in the matter below."

"I was recently suspended because my end of

probation medical showed a positive reading for cocaine through hair analysis. I do not use cocaine or any other illegal drug. I have been tested on numerous occasions in the past two years through urinalysis and the results were always negative."

"During these past two years as a police officer I have never been late or taken off one day. Also, for the past 17 months my assignment as an officer has been in a housing development. Working inside these buildings I have been exposed to crack cocaine smoke, and dermal absorption of residue from empty bags and crack vials."

"Twenty-four nanograms per 10 milligrams of

cocaine, no cocaethylene, and a trace of benzoylegonine." My question is, what do we say to this guy?

DR. AUTRY: Again, please feel free to submit the rest of that for the record.

I have to say this conference, for all of its

science, which has been a lot, is probably going to go down in history for the place where the Bubba syndrome was invented.

Next up we have Harry McCoy.

DR. MC COY: Good morning, I'm Harry McCoy. I'm Founder and President of Medtox Laboratories. I was hoping for more than five minutes this morning, so I'm going to try to shuffle everything I wanted to say in just a few moments.

First of all, I would like to make mention of the

fact that I don't want to lose sight of the fact that the original federal regulations that came about a few years ago for urine testing and mandating accreditation inspection, proficiency testing, I think all of us have to agree raised the level of general toxicology performed in laboratories

across the country.

As our laboratory, being one of the original 10 laboratories certified, I saw each 6 months, the federal inspectors and all the other inspectors coming, all the challenges with proficiency testing, all the improvements that were throughout the country. I think that as we are considering other methodologies, we need to consider that as well.

I hope indeed that as we look back at conferences and we tend to remember something significant, I hope that we don't remember this as the Bubba conference. I hope we remember this as a conference where there was a decision made to embrace new technologies, at the same time remaining true to the ideas of protection of the rights of the employee, and having

integrity and good documentation.

As an example, many of the alternate technologies mentioned the use of tandem mass spectrometry as being crucial to their use. I think that we should have regulations allowing us to use such devices and regular urine testing as well.

I think that when we are considering the almost implemented opiate standards, increasing thresholds, it should be possible to consider looking at lower thresholds to confirm presence of heroin. I think everybody must agree that the main reason that we are screening for opiates is to identify the heroin users. There are many cases in our laboratory where we identify lower concentrations of heroin, with lower concentrations of morphine that we will be missing with the proposed standards.

One thing I have always been very proud of in our fields of clinical and forensic toxicology is that our proficiency testing and our regulations are based on performance rather than methods. I don't want to slam any other fields, but one problem I think in environmental toxicology are the method-based performances which I call regulation of mediocrity, rather than moving towards excellence of science. So I think it is very good that we have performance-based testing. Of course the most methodbased regulations we have is in this area.

Since nothing has beeped at me yet, I would like

to address a few of the issues that were discussed about onsite testing, because I think they can be considered. I think one of the problems identified was two people show up at a collection site; one person screens negative, the other one screens presumptively positive. The negative individual gets the job.

I don't think that's right. I think there are a

few ways to address that. One is to only test post-offer of employment. I think it's very reasonable that if the person does prove the screen presumptively positive, they still have a slot for the job, they just need to wait a few days.

It adds to the cost of the program. There are people who won't like that, but I think it is the only way to have some fairness.

I think there should be a requirement for a set percentage of all of the screens to be sent to the laboratory, whether they screen negative or positive, and that that should be part of the program. I think then all co-workers, supervisors, employers, everybody will not immediately assume, since they don't have an immediate answer, that it will ultimately positive. I think that should be perhaps a 10 percent, similar to the existing NRC program for instrument-based on-site testing.

I think even devices could be randomized to have a 10 percent random

ability to trigger a positive for something. I think that probably should not be identified

as a drug. Maybe that portion should be blinded is a big issue to consider.

All these things I think could also help avoid the Bubba syndrome of having a known percentage of specimens that are going to be needing to go to the laboratory, not necessarily positive.

Also, adulteration -- I think we need to realize that the on-site testing devices are not identical. There has been discussion the last couple of days about the difference between heterogeneous and homogeneous tests. I feel fairly confident in talking about this, since my company has FDA cleared tests in both areas, but there are some differences in the susceptibility to adulteration, and I think those can be addressed as well.

I do have other comments to submit in writing.

DR. AUTRY: I might just make one comment about

the issue of post-offer testing. Most -- in fact, I can't think of a single employer that I have talked with over the past several months to several years that does testing before offer.

With the advent of the Americans with Disabilities Act and of course the RIA Act which has been in place for many, many years, I think most employers do make post-offer testing their standard. I think certainly that is to the employee's advantage.

Next, Donna Smith.

DR. D. SMITH: I'm Donna Smith, and I am a recovering bureaucrat. It certainly feels good to speak from the public comment side at this forum, in comparison to where I have sat and stood before.

For the past two and a half years I have had the distinct privilege, challenge and sometimes the pain of trying to help thousands of employers implement the rules and regulations that I helped develop, conceive and write. I have found through that process though perhaps an amazing thing, and that is that the rules, the guidelines, the science, the policy and the procedures that have been put in place over the past 12 years, first with the Department of Defense testing programs, later with programs in the federal workplace, and then in the private sector by and large have been very successful at what they started out to do.

While the procedures may not be perfect, while the policy may need adjustments, basically the science was sound. From that science, we were able to achieve the original objectives. I would like to use my time to review just basically that we not forget amidst all of our discussion about new technology, about the need for convenience, for speed, et

cetera, what we set out to do.

We set out to insure that in drug-free workplace testing, that no employee would be falsely or wrongly accused of being an illicit user of drugs. We set out secondly to deter people from using illicit drugs in the workplace, in the hope that that deterrence would result in improved safety and productivity. We never set out to search for the last picogram or fentagram or for every single user.

Thirdly, our objective was to insure that the resulting testing programs were in fact fair and equitable for every single person who was subjected to them.

We have come a long way. We have come that way

with the Department of Defense, the Department of Health and Human Services, my own Department of Transportation days, and other federal agencies, the Nuclear Regulatory Commission, because we have done our homework, because we haven't jumped out when urine testing was there, and there were labs that said they could do it, but instead we waited

until we could put in place a national laboratory certification program, a proficiency program, an inspection program.

Maybe the government does move slowly, but I would suggest that that slow movement to insure those three objectives is in fact our strength. I do think there are possibilities for alternative technologies. I think, however, as we explore the science, we must explore that where we get that specimen from at the collection point is an essential issue.

Thirdly or lastly, how we are able to interpret those results knowing that the science is sound is another very critical and essential part of the program.

The program has survived it has been a three stage program of checks and balances, and it has endured and it has improved. As Harry McCoy said, we have been able to come to new heights technologically, scientifically, and I believe programmatically because of those checks and balances, because of the procedures that we built in for obtaining the specimen that is forensically supportable, to the procedures and the science that we have in analyzing the specimen that we have obtained.

Lastly, the checks and balances of medically

interpreting those results all for the end result of insuring that there is not a letter as was read to us, that a person's job is in jeopardy because even though the analysis showed drugs, that individual was not an illicit user.

If we lost sight of those objectives, then I think we have done a tremendous disservice to the journey that we have taken over the past 15 years.

Thank you.

[Applause.]

DR. AUTRY: She may be a recovering bureaucrat,

but she has lost none of her speaking abilities.

I have to say that there is an irony, and that is whenever a bureaucrat or a politician retires or leaves or his or her job, and they have to live by the rules that they wrote, it really gives them a different perspective.

Next is Christine Moore.

DR. C. MOORE: Thank you. My thanks to the Drug Testing Advisory Board for giving me this opportunity. My name is Dr. Christine Moore, and I am the Lab Director of U.S. Drug Testing Laboratories in Chicago.

We carry out testing, and therefore the use of

hair as a specimen in workplace testing would indeed create new business for us, however, at this time I feel that hair is not an acceptable specimen for workplace testing, although it does have some utility in other areas.

The main reasons for my reluctance to embrace hair as a workplace specimen at this time are environmental contamination and problems with racial and color biases, which have been discussed extensively over the last few days and also this morning.

Over the last three years I have attended four

conferences entirely devoted hair testing, and have read extensive literature on this subject. With all due respect to the Psychemedics Corporation, no reputable scientist has been able to reproduce their data in either of these areas.

In an effort to be somewhat constructive, however,

I would just suggest that the board continue to monitor hair testing literature for research which would resolve these two areas of concern, at which time I'm sure that this issue will be revisited, and should be revisited, because hair has some definite advantages over urine.

Finally, as Dr. Selavka pointed out yesterday, not

all laboratories involved in hair testing use the same procedures, controls, calibrations, all those things, and standardization of those things is an essential part of any federal drug testing program.

So to summarize, these issues need to be resolved in my opinion, before hair can be accepted for workplace testing.

Thank you.

DR. AUTRY: Joseph Manno. Would it be helpful if

I left the timer up here so you can see your own time?

DR. MANNO: It won't help me. I had to write this down, because I'm a professor and I can't say anything off the cuff that takes less than two hours.

I'm a Professor and Director of the Clinical

Toxicology Unit at LSU Medical Center in Shreveport, Louisiana. In that function I teach toxicology and pharmacology to medical students, allied health students, graduate students, residents and the community. Our group also operates therapeutic drug monitoring and a forensic hair and drug testing laboratory, and we conduct clinical research into drug effects on human performance.

I thank this group for taking the time to present this symposium which was free, unlike the soft symposium which you have to pay for.

I would like to make a comment that in your

deliberations regarding alternative drug testing technologies, that you consider the use of screening only laboratories under the broad category of on-site testing. Developing criteria for certifying screening only on-site laboratories would provide numerous benefits.

Turnaround time for the 95 percent of the

specimens that screen negative could be decreased significantly to several hours or even less than an hour depending on the technology used. It would allow for the utilization of thousands of clinical laboratories already certified by CAP and/or CLIA for clinical testing to be certified for FUDT drug screening.

It would decentralize drug testing and make more information about drug testing available locally in smaller communities by having some people that know about drug testing in your community to answer questions. It would also provide some guidance to clinical collection facilities and help enhance their education.

Certification could be handled through the NLCP,

and on-site inspectors could be trained by NLCP and come from the state inspectors already certifying labs for CLIA, and be supplemented by current or newly trained NLCP inspectors. The cost of on-site inspection could be dramatically reduced from the current cost for full FUDT certification. Existing PT programs could be used to help conduct proficiency testing of these laboratories.

These laboratories could choose technology based

on desired turnaround time, cost, and other locally determined factors. A recent TAP survey, as I recall for screening only indicated that 47 percent of the participants in that screening program were using technology based on the triage test. So there are lots of laboratories doing a variety of technology out there already, and they are doing very good quality work.

The Louisiana Drug Testing Law, which was passed

in 1991, is based on following federal guidelines, however, that law permits screening laboratories to be certified by the state. The availability of support and expertise from NLCP would enhance our program, and could also encourage other states to certify programs, and again, make a screening laboratory something that is functional and

credible.

The program would offer employers options that

would balance cost and turnaround time to meet their individual needs. Additional revenues generated from these laboratories might also enhance research programs for the NLCP.

Thank you.

[Applause.]

DR. AUTRY: Thank you, Mr. Manno. Next up is Ken Edgell.

MR. EDGELL: Good morning. My name is Ken Edgell.

I'm with the Department of Transportation in the Office of the Secretary of Transportation, and on their behalf I would like to thank the Department of Health and Human Services and SAMHSA and the DTAB members for putting on this meeting.

Your hard work and your efforts have produced some very interesting and enlightening information.

I would like to talk about just three things very briefly. One, I would like to put Bubba to bed. In the Department of Transportation with our alcohol testing program, this was something that we certainly considered, this confrontational setting in the alcohol testing arena.

Typically, the drug test had a period of time and

three different entities, a collector, a laboratory and a medical review officer, and a period of time for cooling off of this individual who might be angry over the positive test. We considered in the breath testing you have the breath alcohol technician, who combines all of those three

elements into one person over a matter of minutes rather than a matter of days.

As far as we can detect from calls that come in to our office, the Office of Drug and Alcohol Policy Compliance, of which we get about 100 per week, and information that comes from the operating administrations, program managers, the operating administrations within DOT, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, et cetera, the reports that are coming in from them, this is not an issue, this confrontational issue, at least it has not been raised to us as an issue.

Secondly, in yesterday's presentation on reporting results, I believe that I heard it stated that the DOT would turn its head the other way perhaps in a situation where actions had been taken on screening results. In a few words, that would be completely contrary to our program and our policy.

Our rules are clear, that no adverse personnel

action be taken on a screening result. A negative on a screen for both drugs and alcohol, no further testing is authorized. If the screen is positive, a second test is required. In alcohol, granted by definition, that confirmation test is a reaffirmation of the first test.

It is possible to use in breath the same

instrumentation, but the second test and the confirmation test result is the result of record that for drugs, goes to the medical review officer to discuss with the individual, and then verify positive or the final result would be passed to the employer.

With alcohol testing it would be the breath

alcohol technician who has the final result and passes to the employer, who would take action on the individual.

Thirdly, I would like to reiterate what Donna

Smith said. The Omnibus Transportation Employee Testings

Act, that federal law was enacted with the following words, "in the interest of public safety." The secretary of transportation has also reiterated that any time someone

boards a train, a bus, a plane, a transit system, that those responsible for the operation for that mode of transportation is drug or alcohol free.

So clearly this is a safety first program,

however, the program that was established by DHHS and carried on by the Department of Transportation -- and currently we have about 8 million people subject to drug and alcohol testing within DOT -- we have

limitations and protections.

We limit the individuals within the tests to

safety sensitive employees. We have gone to great lengths to protect against the false positive and the positive that can be explained through the legal alternative explanation for medical use in the case of drugs.

The MRO protects the employee who has a positive result that can be explained through a valid medical explanation. The test results for the verified positive individual are protected in that they are released only to individuals with a need to know, and who can take action to remove that individual from their safety sensitive position.

So that it is our concern that these protections

are maintained, and that the DTAB members factor in the worth of these protections to all their considerations and recommendations resulting from this meeting.

Thank you again.

DR. AUTRY: Thanks, Ken.

Next is Carl Selavka. Weren't you a presenter? DR. SELAVKA: I'm Carl Selavka from the New York

State Division of Criminal Justice Services, and my caveats of yesterday still apply.

I handed this out to the board, and so I will be reading quickly. Several common workplace testing scenarios other than pre-employment testing include: post-accident testing, for cause testing, testing related to return to duty after a significant time away for injury, illness and rehab, and random and routine testing of personnel and safety in security sensitive positions.

Drug testing of any kind is but one aspect of investigating fitness for duty, monitoring compliance, or investigating significant departures from normal actions or behaviors, but in these situations the employer desires information which assists in fully evaluating potential contribution of drug use to the testing individual's fitness, performance and/or behavior.

How may complementary tests of alternative

matrices assist in these situations?

Post-accident -- the employer needs to immediately determine the possible contribution of drug use to the accident, and may also be concerned with historical use patterns if drug is determined to be present in the individual at the time of the accident. Breath and/or saliva alcohol testing is indicated in this case.

In addition, if blood cannot be drawn immediately, saliva offers an alternative for determining the presence of drugs in the individual's bloodstream just after the accident. If drugs are determined using blood or saliva testing, hair testing can be used to query whether the individual is routinely using drugs, or this was an apparently isolated incident.

For cause testing -- the employer recognizes aberrant behavior by the employee. An evaluation strategy similar to that used in post-accident testing may be proposed. The immediate contribution of drugs to behavior may be determined using blood, or the lessened base of saliva testing.

Urine testing, with on-site evaluation

potentially, may be attempted. Positive results in saliva and urine may lead to the use of hair testing to assist in the design of an appropriate treatment or other response to the problem.

Return to duty situations -- the employer may be concerned with drug use on the day the individual returns, as well as drug use over the period of absence from work. Urine testing supplemented by hair testing would provide information to address these concerns. For an employee returning to duty after drug rehabilitation monitoring of sweat using the patch technology or periodic hair testing provides prospective verification of continued abstinence.

Random and routine testing scenarios -- convention

urine tests may be confounded by several factors. Specifically, opiate positives in which 6-acetylmorphine is not detected, no admitted prescriptions explain the result, and no clinical signs of heroin abuse are present, are routinely not verified by MROs.

In these situations, the tested individual could

be offered the choice of hair testing for heroin in 6acetylmorphine to check historical use patterns, or could select prospective sweat or hair testing for heroin in 6acetylmorphine for a period of time to verify abstinence. Similarly, adulterated urine samples could trigger the collection of hair for testing.

Thank you for allowing me to offer these

scenarios.

DR. AUTRY: Next we have Howard Taylor.

DR. H. TAYLOR: My name is Dr. Howard Taylor. I'm with National Safety Alliance, a third party administrator for drug and alcohol testing.

As a former SAMHSA laboratory director and current NLCP inspector I guess I look at this process and boil it down into the KIS principle; keep it

simple. I placed myself in the role of the MRO to evaluate hair testing. I found the science very confusing, much disagreement.

I guess I would boil it down into saying currently the situation exists where the MRO has complete confidence in the laboratory, in the science. There is a way in which if a donor denies the use, the MRO can go back to the laboratory, discuss the results with a toxicologist, feel comfortable about those results.

As I look at hair testing, I guess I go back to

see what do we know, and what makes it confusing? We know there is external contamination. We know that the drugs bond to melanin.

As I listened to Dr. Baumgartner's talk in finding that the washing steps are very critical in order to remove external contamination. The drug essentially is bound to melanin. There is a melanin wash in which the melanin is removed. If the drug is removed externally, and is removed from the melanin my question is, where is the drug to begin with? Where does the drug start out?

What concerns me I guess, is as other speakers

have noted, is the lack of standardization. I would ask that the hair testing laboratories submit data to the Drug Testing Advisory Board to verify their claims; that the external contamination issue is put to bed; that the procedures and techniques are solid and sound; and MRO does not have to answer this question of denial, and can feel comfortable with the test results.

Thank you.

DR. AUTRY: Thank you, Mr. Taylor. Next is Robert Bost.

DR. BOST: I am Robert Bost, formerly medical examiner/toxicologist in Cleveland and Dallas. I am

currently offering private consulting services in the Dallas area. I am a CAP and NLCP inspector, and as the organizer of the first of these conferences seven years ago, I wish to commend the board and SAMHSA for the efforts, for the planning, for accumulating a fine panel and a marvelous forum for us to get together and discuss this subject. I have thoroughly enjoyed the two and a half days here so far.

I have one small concern, but I think it is

something that was inherent in the initial urine discussions that we have at least not mentioned yet. As I understand the concept of on-site testing, that is analysis that is performed at the site of the collection. I am aware of at least one location where the collection is done at the employment site by employees of the company. They would have an opportunity to recognize, to know the donors.

With the urine testing one of the primary concerns was segregation of the identity of the donor from the laboratory specimen until these are combined in the hands of the MRO. My concern is that as currently described, the onsite testing would permit the test result to be in the hands of someone who recognizes the donor, and I question whether that is consistent with the guidelines, the principles that we have operated under for these several years, and I request the board to give that consideration as they think about the on-site testing program.

Thank you.

DR. AUTRY: Thank you, Mr. Bost. Next is Meggin Garrett.

MS. GARRETT: My question has been answered.

DR. AUTRY: Thank you. Barry Sample.

DR. SAMPLE: Hi, I'm Barry Sample; appropriately named B Sample. I'm with SmithKline Beecham Clinical Laboratories, and I have one question for the board and for Donna before I start. Since I'm from Atlanta, Georgia and I drive a pick-up truck, I want to know if that makes me a Bubba?

PARTICIPANT: Yes.

DR. SAMPLE: I wanted to address my comments today primarily to the issue of on-site testing. We have heard a lot about how the on-site testing is very similar from the regulation standpoint, to the current guidelines. While that is true, there are a lot of specific issues relating to the on-site testing that need to be considered by the board and by the Department of HHS, so we can develop some guidelines to insure the fair, consistent application of the program to all the donors in the manner similar to the current program.

Going down through the process, and like our specimen bottle tour, starting with the collection, one of the issues I would raise for consideration is how many specimens need to be collected? Obviously, we are talking about specimen collection in this scenario, so we are going to have at least two specimens to begin with.

We need yet a third specimen to perform that on-

site test, so that we can retain the sanctity, the integrity of those two specimens, the primary specimen, the split specimen that would forwarded to the certified testing laboratory in the event of a positive test.

Now obviously if the on-site is in the collection cup, as is available from some vendors, then perhaps you could get by with two cups and not three, but I think that is a question that needs to be answered.

Another issue that was addressed by Dr. Bost just before me is if you are doing on-site testing, that should be done separate from the employer site, again, to help segregate, separate the testing process, the

collection

process from the co-workers, from the employer that may come to the wrong conclusions based on some presumptively positive specimens that ultimately are going to confirm as negative.

Another consideration from the collection

standpoint is how many forms are you going to use? Are you going to use a separate form for the on-site test, and then use a standard form for the test that will be forwarded to the laboratory? Or would you try and modify the current forms to allow for the on-site test, as well as the final testing after going to the lab?

For the on-site test itself, training is a very, very key issue. I have heard a lot that there is a lot of subjectivity, issues of color differentiation, and how do you insure consistent grading of those color changes to insure consistent application at the cut off?

Adulterants are an issue certainly. There is not

a mechanism, such as an internal QC check to address adulterants, and how are you going to test for adulterants in an on-site test?

External QC sounds like 125 percent of the cut

off. We're not going to consistently test positive as we are used to currently. We may need to have higher concentrations, but then are we really testing the cut off in the sense that we are used to, and verifying linearity at the cut off?

Reporting from that on-site test, should that go directly to the client? Should it go to the MRO? If there is a presumptive positive, should that information be transmitted to the medical review officer prior to having a confirmed verified positive from a laboratory standpoint?

I certainly recommend a retesting of negative

specimens from a QA standpoint on the order of 5 or 10 percent, however, when you do that, that raises the issue of what do you do if you have a negative test on the on-site test, you send it to the laboratory, and there is a clear positive.

I'm not talking about borderline positive, but a clear positive on that QA test. Do you then go back and change the result from a negative to a positive? So there are a lot of issues surrounding how do you handle that situation.

From the confirmatory lab standpoint I would recommend that both a screen and a confirmation occur. It is not really a valid screen in the sense of we think of a screen on that on-site test. We need to be doing a full screen and confirmation at the test site.

That concludes my comments. Thank you.

DR. AUTRY: You guys are amazing the way you are staying on time today.

Next is Hashim Othman.

DR. OTHMAN: Hi, my name is Hashim Othman. I work for Quest Diagnostics Laboratory.

This person asked most of my questions, however, I have a few questions regarding the on-site testing that I wasn't clear about. For example, we had eight speakers talking about on-site testing. It would have been very, very helpful to see some slides on what these devices look like, how they work, how they operate.

Also, I wasn't clear on a few issues, for example, how many of these devices exist in the market; whether they all work by the same mechanism; what type of reagents do they contain; how much urine is needed to conduct the test; how long does it take for the test to be completed; how borderline results are read, if they fit the color test; is it left to the person who is conducting the test to say this

> is borderline positive or negative, something like that? Whether the specimen that is sent to the

laboratory based on the positive screen needs to be

rescreened at the laboratory to establish dilution factors, since the screening results is just a color test, and it does not provide any indication on the positivity of the specimen?

Also I had concerns about the documentation of the test results. How do we document test results of color tests? Do we just say positive, negative? There is nothing to be recorded, except if you want to make a photocopy. That photocopy must be color photocopied, because if it is in a black and white copier, you cannot even distinguish the color.

The last question I have or that nobody mentioned

or talked about is the economy of the on-site testing. Is this on-site testing cheaper than the laboratory? How much cheaper is it than the laboratory? If the on-site testing is costing $24 per specimen, and the laboratory test is $1520 what do you do? Most people want to save money these days, so would you go with on-site testing, or would you still rather send your specimens to the laboratories?

Thank you very much.

DR. AUTRY: Thank you, Mr. Othman. Next is Ray Kelly.

> DR. KELLY: My name is Ray Kelly, and I am

Director of Toxicology at Associated Pathologist Laboratories. We are SAMHSA certified and CAP accredited, and do about 50,000 employment hair tests a year. You will note that I do fit the phenotype.

I would like to urge the board to stay in touch

with this issue of new technologies as it develops. I think it is tempting because of the controversies to maybe just sort of throw up our hands and kind of leave those of us who are doing employment hair testing or alternative samples out there.

I think I should add parenthetically that APL's posture on some of these controversies is full disclosure of the scientific facts both to our clients and to employees, rather than the development of mythologies.

I do think that there is a big contribution that

can be made when an area like this can be overseen, can be regulated, can be inspected and criteria can be developed for acceptable performance at least in the areas where it lends itself to that. I include such areas as: equipment, methodology, personnel, SOPs, security reporting and the like.

I think it is important that somebody take the

leadership in this area, so I appreciate the fact that we have been able to have this meeting, and that SAMHSA has, over the last few years, taken an interest in this issue.

I would propose that the board monitor this in an ongoing basis, consider some preliminary steps toward overviewing this area, again, in those areas where there is a possibility of doing it, and should continue to receive input.

One of the things that disappointed me I guess as somebody that is with another hair testing lab besides Psychemedics is that even though there are five laboratories, except for the reporting issues, there was very little representation of any other laboratory. I think it is important that the board continue to get input verbally and in writing from those other practitioners as well.

I would like to make one other final comment in regard to on-site testing. That is it seems to me that if

you do on-site testing as an employer, you are going to be taking one of two actions: either putting someone to work that has a presumptive positive result, thereby assuming liability for that person's actions; or second, you are going to keep them off work, based on a presumptive test which in the case of opiates, might be wrong more than 90 percent of the time, and in the case of amphetamines, depending on the specificity of the immunoassay could be a very significant portion, up to 50 percent or so.

It seems to me that is kind of a no win situation legally speaking for the

employer. I think repeating the test doesn't do any good, because again, whatever deficiencies it had the first time, it will also have the second time, so in that respect it is not the same as alcohol.

Thanks.

DR. AUTRY: Thank you.

I will make a comment now that I was going to make later on, but I think it's an appropriate follow-up to that.

That is invite any one at this meeting who has published information that might help inform the board's deliberations please submit those to us. They will considered in our deliberations.

Secondly, that if you have your own personal, unpublished data that you think might be helpful, to please consider submitting that to the board. I must tell you, however, that since this is a public forum, and since the board is a public board, that all that information is foible, so that may dampen your enthusiasm for that, but it certainly would be helpful if some of you consider that. I think that might be particularly true if there are any SOPs that relate to the alternative specimens and alternative technologies that might be helpful.

As you know, or if you don't know, I will tell, working as a bureaucrat there are a lot of limitations in terms of what you can and can't do. One of the things we cannot do is keep information out of the public. So anything that we have is public record. I must tell you that up front.

Donna, we have some questions that were left, or comments that were left, and I think it would probably be appropriate to read those into the record at this time, and then do you want to take a break before we go into the discussions? What is the board's wish on that? Yes? Okay, we'll read these.

DR. BUSH: Following our instructions, for those

who could not be here today, should they have a comment or a question they could make it available to us through writing it on an index card. I will tell you that each and every one of these that was submitted to me does not come with name of person who made the request and their affiliation. In the one case where that happens, I will read that into the record also.

Question: As part of this review, will the DTAB look at criteria which should be used by on-site testing via instrumentation such as emit, COBAS (?)? NRC and nonregulated employers often use such testing. They require similar scientific and administrative protocols. In parenthesis here it is, please be the advisory board for all workplace testing, not just DHHS and DOT.

Will the DTAB address alternative or alternate

urine-based cut off levels for use by NRC and/or nonregulated employers? Whether you like it or not, the DHHS standards are industry standards for non-regulated programs.

Another card from another submitter. As the board

is reviewing requirements and standards for the various

methodologies and alternative devices will it also be reviewing the current forensic urine drug testing standards in the same light?

For example, if the ROC plot is considered best practice for establishing cut off levels, will the board review the current urine testing cut offs by the same standards? Or whether physiological and biological issues such a pigmentation and hair are also discussed concerning urine testing, i.e. differences in metabolism may create different results from two identical doses, yet we do not worry about that.

The third card of questions, while there has been appropriate attention given to false positive laboratory results resulting in virtually no false positives from the GC/MS confirmation process, there has no similar emphasis on reversing false negatives in the screening test. An employee expects no false positives. He also expects low levels of false negatives, yet he may not get this value.

What is the acceptable level of false negatives

which an employer should expect as a part of the employer's blind specimen program? Why aren't there formulation standards for employer blind specimens? How can an employer know if the blinds are really measuring test reliability?

The fourth card; this one does have attribution of source, Steven Troxel from Technical Services Manager, Diagnostic Reagent, Incorporated.

To Dr. Ed Cone: Will the fact that only RIA and Kim's Technologies are sensitive enough to detect the NIDA five drugs at the stated cut off levels using hair, saliva and sweat be a major factor in initializing a program using these types of specimens?

Two, could Dr. Fogerson, Dr. Niedbala and Dr.

Baumgartner review how they propose to automate large batches of sweat patch/saliva collection devices and hair processing respectively.

For Dr. Baumgartner, a couple more have just been given to me. If wash kinetics analysis is so important for other drugs, why not apply it to marijuana?

Comment -- why would an on-site negative result need to go to an MRO? Breath alcohol results either negative or positive are not reviewed by an MRO. One major reason to do on-site testing is to significantly reduce

turnaround time of negatives. That is how these products are being marketed in the real world, with persons in company's human resource department performing the test, like a screen breath alcohol.

This type of testing is more expensive than

sending it to the laboratory. If the results must go to an MRO and then back to that company, or testing must occur someplace other than at the company's location, then there is no market for this product.

Comment -- on-site testing is exempt under CLIA if it is used for workplace drug testing.

Question for the panel to discussion. If recommended principles for on-site testing should include: (1) use of quality control; (2) confirmatory testing; (3) MRO review; (4) training; and (5) proficiency testing, how could these safeguards be addressed in drug testing on-site by the average consumer?

To MROs -- it was stated Tuesday that currently 80 percent of positive screening tests for opiates in urine are overturned after GC/MS confirmation and MRO review. Please approximate the percent of similar accuracies when considering amphetamines in urine and cocaine in urine. Is there any data to approximate these same parameters in saliva, sweat or hair testing, and with typical on-site

devices?

This is an important consideration since many users opt not to do confirmation testing because of cost. Approximately what percent of employers are willing to pay

for confirmation testing, rather than making their decisions on presumptive screening test results? Ditto for insurance companies and ditto for treatment facilities or hospitals.

To the hair testing folks, please explain the

binding process that takes place when you spike calibrators and controls. What data supports that this create (matrix) simulates hair behavior? How does the high imprecision observed with your sample and assay system affect the reporting process?

That is the summary of all the questions that have been received on cards.

I have something I would like to read. While

watching an early morning show on TV this morning, I saw a story I feel compelled to relate to you. The Department of Army is reported to have a supply of large equipment such as tanks and other vehicles that will go to surplus. The Department of Army is making these available for purchase to legitimate established law enforcement agencies.

Smith County Texas Sheriff's Department has purchased two of these vehicles. One is a tank, and one is another large armored vehicle. The sheriff's department has aptly named them Bubba 1 and Bubba 2. They were named Bubba because this name implied a mythical character nobody wants to confront.

I hope we can leave the name Bubba with the

armored vehicles in Texas, and not as a legacy of this scientific meeting.

Thank you.

[Applause.]

DR. AUTRY: With that, let's not only give Donna a break, but let's all take a break for 15 minutes, and be back here at a 10:15 a.m.

[Brief recess.]

DR. AUTRY: Before I go into how we are going to run the rest of this morning, we have a late arriving comment, which is signed DRZ Management. That's all the information I have. I will read this into the record.

As a TPA and non-scientific observer, I hope that before any of the alternative technologies are put into place at the regulatory level, that focus groups of industry end users, collection sites, labs, and MROs from areas without financial stakes in the area are put together to take a hard look at the possibilities.

Or the option is an alien abduction like hair

removing, oral fluid extracting, sweat collecting free for all, cost unknown. Thank you.

Agenda Items: DTAB and Panel Member Discussion

Let me tell you what I think we are going to do, because there have ben a whole lot of comments and questions that have been raised this morning. What I would like to do between now and the lunch break is to give the board members a chance of asking any questions or raising any comments that they have based on what they heard throughout the meeting up this point.

Then I would like to give the presenters in particular, who had questions that were raised about their comments or their areas, to give them a chance to respond to some of the questions and concerns that were raised this morning. When we get to that point, I will ask each respondent to try and limit themselves to five minutes, and I will set the infamous timer, if I can find it between now and then.

So let me turn to the board and let each one of

you who have comments or questions or concerns or answers to some of the questions that have been raised, just to give you a chance to respond first.

DR. JACOBS: I was unsure when I came here as to exactly what the outcome would be. Whether we were to come to a conclusion today or in the near future. I am even more unclear now. I think that we're somewhere between saying these technologies are totally unacceptable, and fully acceptable on the equivalent of urine testing. We have to decide where, in between those two ends, we might go.

To help clarify where we are going to be in

between that, I would like each of the technologists to address what they see as the purpose or the future role of their various technologies, how they would correlate the numbers they get with established urine testing cut offs and interpretations?

For example, there is a proposed opiate change

that will increase the cut offs. How does that relate to most of what I saw here that looks like you are testing at level of detection?

I think we need to get clear, published, reproducible procedures if at all possible. We need again, all papers and data to support any positions that you have, that can help us come to a conclusion as to where in between these two ends we might be able to get some resolution.

MS. BAKES-MARTIN: My interest, as I sort of

deliberate this, because my experience is mostly in the screening testing, and also in the clinical area is to try to make an evaluation of performance once it gets out into the field. I don't mean once a device goes out and you test personnel that are in the field. I am really interested more in people in the field using the device.

What that brings me to is that I would really be interested in seeing some further information on some of the proficiency testing data that was referred to in some of the presenters. For instance, for the point of care testing we saw some information on the number of participants that were enrolled in CAP programs and AAB programs.

I realize as the presenter mentioned, that those

are for medical purposes, however, I think it would be beneficial that if the information could be collected from the summary reports -- those providers do provide public summary reports -- that would be helpful to us. We could then see what the performance of on-site devices are like.

Also in hair analysis, the presenter offered some

proficiency testing data. I believe he alluded to the point there had been

some improvement in that data. It would be helpful for us to see that. I didn't know if he was planning on offering that or not.

It would also be helpful if we could see the

actual data points. I'm not asking for laboratories to be identified, but it is difficult when you see aggregate data, to be able to determine what you are seeing. Those of us that are in the clinical area do become concerned with performance outside of plus or minus 3SD data, so it would be helpful for us to see if there are clusters in that data.

With the other alternative technologies, I know

that you mentioned that there is no proficiency testing program at this point, however, you may have some data or information that would get to the same sort of question; variability once these things are out in the field and used by -- I'm not going to say non-professional personnel, but we would be concerned about the usage of these throughout the country by maybe not the best trained personnel.

So that is the type of information I would like to

request.

MS. MALLORY: I'm interested in looking at standardization of the different devices such as the onsite. How many of them are out there? Basically, how are they different from each other, and how are the controls on board? I'd like to be able to see those and see where we are with just what the gamut is, what is on the continuum. Where are we, and how do we get to standardization of this?

Also, as we consider this, and we bring these into

the workplace drug testing arena, would there be further development of these devices? Would there possibly be an on-site testing with the saliva or the sweat patches? I just want to see where the technology is going or are we there at this point.

So I would like to get a little bit more information on how these devices work, and the differences between them.

DR. KWONG: A lot of things I want to bring up, Rosemary has just addressed, but I would like to add on one

more point, and this is specifically for the on-site testing arena. I think our concern about the training, and how we make sure that the on-site testing collectors are properly trained, and it is certainly something we would like to get more information on.

Is there any proposal or ideas that the on-site testing folks have been working on that can be shared with us to see how you plan to train these folks and continue education, or how to certify them?

DR. PINDER: I think one of the issues that I'm

very much interested in having some clarification on, I guess it's basically because of my background. Much of my background has been in post-mortem toxicology, where you have somewhat of a problem when you are trying to deal with calibrators and controls, and you are using tissue like brain, liver and bile.

In the presentations, I noted that I believe Dr.

St. Claire said that with the sweat patch, in producing a calibrator she places the drug on the patch itself, extracts it from the patch to produce a calibrator.

I believe Dr. Peat mentioned that he places the

drug into what he calls a preservative fluid. This is a fluid that the saliva patch is placed into.

So there are differences in how these calibrators are created. Is there an advantage to placing it on the patch? Certainly you would think that there is some degree of inefficiency in extracting material from the patch into the solution, and if you don't place it on the patch, if you simply place it into this preservative fluid, then you are eliminating that matrix altogether.

Of course there is a question of hair. How do you create calibrators in hair? How do you get drug into hair?

There were several slides shown where there was tremendous precision in the recovery of the drug from a digest. So apparently a digest of hair is created. The drug is added to the calibrator. Standards are added to the digest, and then re-extracted.

The precision that was demonstrated may simply

imply that there is no binding when the drug is placed, and how does this approximate drug that is actually extracted from a patient's hair?

So the question of how you create calibrators, controls with the alternative specimens is something I think that a little clarification is needed on.

DR. JONES: I would just reiterate Dr. Autry's earlier comments about our desire for additional data. For those of you straining, this is Skip Jones speaking up here.

I realize that we have received a lot of

information over this past two and a half days. I would not be more than honest with you if I didn't say I personally am rapidly reaching information overload, but I think that this is good. I encourage all of

the submissions of additional data, additional information. Some of the speakers this morning will be supplying us with additional comments.

As an administrative item before we get it, I

think we need to put a time on that submission, a time limit for subsequent activities of the board.

There are some of the questions that have already been raised that I also have. Some of those may not be able to be answered here this morning; some of them might be. One additional question that I have that might possibly be answered this morning also is a particular question to Dr. Sachs. Do you have any information on the interlab variability?

Do you have information on interlab variations?

Do you have any information on how the variations within a given lab, intralab performance occurred in your database that you presented with us?

I would ask also that any of you that might be

submitting data, to give us much data in detail like that as you can. Rosemary raised the issue about we don't need to identify who the individuals are in there, but if you see the raw data, and don't see a glomerate data, it gives us a much better feel of how we can look at that database and what is happened in whatever it may be, be it sweat, be it saliva, be it hair testing.

DR. WILKINS: Thank you. I don't want to leave

the urine drug testing people feeling left out of requests for information. Several of our speakers have emphasized the point that they would like us to consider in our deliberations comparing the alternative matrices and on-site testing devices to the expectations for urine, and certainly that is important.

One individual -- and I regret I cannot remember

who asked the question -- asked for specific information on gender/ethnicity effects in urine drug testing. What I would request is that if someone has data from a large scale study or a large population that they can provide to the board, so that we can officially consider it as part of our deliberation for comparison, I think that would address that person's comment to the board that we consider that information as well.

I'm not sure if it is widely available right now.

I know there are many small scale studies, but I don't know

if there are some larger studies that might be available. Thank you.

DR. CAPLAN: To reiterate a few of things, I just want to make a couple of comments, because as everybody has said and we all know, it has been a lot of information. There were some challenges given out by the program organizers to sectional chairmen to put certain things together to make sure things were included.

I think we need to separate, as we go forward,

what I might call functionality or the technical aspects from programmatic and policy issues. I believe the board is going to try to look at the scientific issues, and the policy things would come from HHS, DOT and other people later on.

I would encourage -- and maybe it's the people

that were the coordinators for each of the specimens, because one of the I guess inevitable difficulties in putting a large thing like this together is when you get a bunch of speakers, they were giving us our experiences, they

may or may not have kind of covered the field entirely, and been somewhat redundant.

It should be obvious to the people that are presenting that material because there has been discussion, that there are certain problem areas or issues that seem to need more detail or resolution. I think it would help the board a great deal if the coordinators from the six sections could think about what was included, what kind of questions came up, and do you think that in the booklets, in the handouts and things, there is adequate information to answer those?

In many cases I'm sure you are going to agree that there are things missing. Many of these things have been mentioned here already. To try to simplify the process by saying: (a) seems to be an issue; (b) here is the general position that that entity, that alternate technology thinks should be considered; and (c) then this is the specific data that supports that.

I mean to give us 100 papers or piles or reams of things to say, well, if you look at these 52 papers that were published all this time, you are going to find the answer; we might not find the answer that easily. I would like to say, point to the answers.

It's like cause and effect. This is an issue.

Pick an issue -- on-site testing, the reproducibility of the devices, and say this is an issue. Here is the response that we were attempting to give you through the multiple speakers, who obviously gave their own experiences and enjoyed some license in how they were able to present that, but might not have answered the question the way you think it should have been posed, the way it was initially posed to the group.

Then give a very specific and directed response.

We think this is the answer, and here are the data, or here is the study, whether they be a published study or a line in the various statements, or your own data. I think if you could summarize that -- I'm not saying go do another research project, but you have already thought about this in getting this thing together -- summarize that bullet form, I think it would help a lot to focus what we need to look at as we deliberate, and that would be appreciated.

DR. AUTRY: Originally I was thinking about giving each respondent five minutes. My sense is that that might not be enough time for a number of the presenters, and people who have answers to many of the questions or comments that were raised earlier.

So let me try and do this. I would like to try

and give everybody a chance. If we do this by having only one person from each one of the alternative technologies or specimens speak at a time, and then we go through each one of those areas, and then we will come back and start over again. If we can do that, maybe we can keep it to five minutes. Limit your comments or questions at one time to five minutes, and somebody else from your area can get up and pick up, and they will have another five minutes to respond to that.

I am trying to figure out some way to get the

information out without having a free for all is the basic issue. So let's try that. If it turns out it doesn't work, we will see if we need to extend the time to maybe seven minutes, but I'm concerned that if we run it much longer than that, we won't get as much information out as we need to.

Does that sound like a reasonable game plan?

Werner, do you want to be first?

DR. BAUMGARTNER: I would like to make a few

comments. First of all, concerning the Navy collaboration, I am very grateful to them for their initial support, but subsequently they ignored one of the basic tenets of science, which is if you evaluate somebody else's technology, you have to do it in exactly the same way. The contamination studies can be done in exactly the same way, but they did use isotopes and not mass spectrometry.

This issue is very well documented in a number of publications, so I'm not going to into any detail. The CSC press on the book on hair testing discusses all aspects of this controversy, but if you don't use exactly the same technology when you could, then your data is different. It is not valid, and that's an FDA criterion I think.

It is of course one, I understand Dr. Blank's

concern. We share it with them. Of course we know that drug users do deny. The other problem of course is that we have helped the Navy identify problems with passive exposures which result from something that Dr. Cohen showed for instance with the 1 milligram of cocaine passive internal exposure problem, and we have saved the careers of two Navy officers, one for 18 years, showing that they did not use drugs.

I would like to address Dr. Moore's issues. Dr. Moore, I am glad that she is going about passive exposures, because her data shows that she is 10 to 50 times below the cut off level that a consensus on hair testing has recommended. That of course gives considerable concern.

By sticking to this particular procedure, she

ignores the consensus of 100 practitioners on hair testing, which involved wash kinetics and higher cut off levels, although different countries, for different reasons, use slightly different cut off levels.

Concerning her point that one can't reproduce my data, well, as I said, the Navy study is certainly one that has been refuted. The proficiency test by the Society of Hair Testing showed that you can reproduce, people can reproduce data.

It is very important that every laboratory can use the digest procedure for mass spectrometry, and of course our wash kinetic procedures. So there is absolutely no reason at all why you can't get exactly the same results. The screening test is simply a commercial advantage.

Concerning Dr. Kelly's APL position, I would

encourage Dr. Kelly and APL to join the consensus of the Society of Hair Testing. They, unfortunately, still insist on using other methods.

I should also mention that Dr. Kidwell was

extremely helpful at the consensus meeting in supporting the Psychemedics wash kinetic approach, which in a somewhat limited form was part of the consensus. Psychemedics goes beyond the consensus, but that is simply our policy of doing the very best.

I understand there will be some specific questions asked of me later on, so I won't answer them now. I am a little bit surprised that concerning the review office's problem, I think the issue for him was that the -- I have forgotten exactly what the issue was now -- I guess that urinalysis certainly should worry about Cohen's very important study. I think hair is certainly something he doesn't have to worry about. We have a medical review officer training course, and we encourage him to attend it.

DR. AUTRY: Thank you, Dr. Baumgartner.

Dr. Sachs, do we have a copy of the consensus statement in your slides that are in the book? In your books in Dr. Sachs' section you will find

copies of the consensus I think that Dr. Baumgartner was referencing, an extract of it.

DR. NIEDBALA: Actually, there weren't that many questions on saliva as a fluid, so I can start pretty much from a top line approach which is one of the questions from the board, which is how could saliva be used? I think I gave a less than adequate answer yesterday to this particular question, and in general take a step back to thinking about fluids and alternative collection modalities.

Basically, when a physician looks to make a diagnosis, he looks for a number of different indicators all leading down to that same diagnosis. The worst thing for a physician is to have one answer that disagrees with all the other information collected.

So in the field of drug testing, I want to use that analogy, because as we think about these alternative fluids, these different collection devices, our job, your job to the American people, if I can again stay really global, is to provide technology, service, accuracy using good scientific methodologies that can help us in the war on drugs. That's what this is about.

So as I think about the alternate fluids, specifically I am representing saliva at the meeting, but certainly I'm involved in all of the other possible fluids for analysis, I would just say that saliva for instance, and Dr. Selavka had alluded to this earlier very eloquently, at the scene of an accident something like saliva can give an instantaneous result in a manner that is very easy to collect and very easy to use, and has certain benefits.

It is a marketeer's dream basically is what we are talking about here, to be able to have access to all these different fluids to provide information. As far as one of the other board questions, which is where is the technology going, I think I'm seguing right into that as I speak, in that what we will do if given the latitude is we will take in the private sector, all of the information clinically. We will adapt to it technologies that are becoming available.

Some of it I think can be given in follow-up, but there are techniques currently underway, for those of you who read the literature, in the area of drug discovery and genomics that are miniaturizing, that are multi-plexing, that are allowing simultaneous analysis for many analytes at concentrations far below what we are looking to do with drugs of abuse testing.

So if I want to make a broad statement, I think we are really just on the cutting edge of the next frontier as far as technology is concerned. I think we are all going to be surprised by what we see, not only in laboratory-based testing, but on-site testing as well. Saliva, hair,

sweat, all of them simply are the carrier to those technologies, in my opinion.

So from a broad statement, I think what we are

going to narrow down to is as long as we are given the latitude legally, and market pressures will dictate as well, I think this board has the opportunity to lead that effort, to keep an open mind. Not necessarily to say this is urine, so this is the way you have to test it, but to craft guidelines by which new technologies have an avenue to support and to be used by the general population, and be led by professionals who can dictate what is appropriate for the new fluids and the new technologies that are going to become available.

I think that is an opportunity. I said this I

think two or three times, my glass is always halfway full, and so I look forward to this, because it is an exciting time.

Now to answer a few more specific questions, in

the area of saliva, how are calibrators made? I think it's a more mundane question, but in actuality as we look at saliva as a test fluid, there are different collection devices, and we tried to give you a good representation that that does exist.

However, I do believe there are ways in

proficiency, as well as calibrators and controls, and it is actually pretty simple to address this. As a manufacturer of the screening devices, we have not yet had time to take a look at each and every way to collect saliva, but I do believe that because of the samples that are being collected for saliva being somewhat clean in terms of their composition, these are things that we can overcome.

So I don't want to necessarily think that this is

a very large issue as far as the technology is concerned, and that through developmental science, I think it can be addressed.

One other that came from the audience, which is

for saliva, and I know the same question is for sweat as well, what kind of equipment is available, and how can you do testing? I'll revert back to one of my comments during presentation, which is microtider plate technology, which is what we are dealing with, has been used for many, many years in other areas such as blood bank and plasma centers.

These folks protect the blood supply. They are certainly under constraints that in some ways are more stringent than what we have right now with some of the instrumentation used for drug testing.

So I would simply say that as far as throughput is concerned, we can test on average, numbers of samples that are consistent with urine testing now. As far as the equipment, software, et cetera, it is under strict review and is simply being adapted to this industry.

Thanks.

DR. AUTRY: You can always tell somebody that does

a lot of public speaking and they begin the last sentence with a lot of "ands."

Someone from one of the other alternative

specimens technologies? Mike.

DR. WALSH: As the resident gray beard, although some of the nearly gray beards are not here, Yale Caplan is still here with us, and I'm very grateful to the fact that he is, because I think we all spent a lot of sleepless nights back in the middle part of the eighties when we were struggling to put together the program.

I would like to pick up on some of the comments

that Dr. Niedbala just made, because I think he hit the nail on the head in a number of areas. I would like to put a little historical perspective to where I see the board and Dr. Autry's responsibilities today versus where we were in 1985.

Dick Cox and I got tapped in 1980 to be the

liaison with the Department of Defense, and we observed and advised and saw them struggle through the beginning of developing a large drug testing program. Even though it was very controlled within the services, and they used their own laboratories, there were a lot of problems as we started.

A number of us were involved in working with

President Reagan in developing the executive order and knew what was coming. The data that we had at that time, Dick Cox and Ken Davis had published a paper in JAMA in 1985, a survey of laboratories.

If you go back and you look at that paper, you

would have said how did these guys ever think they were going to put together a system that could be accurate and

reliable, and you would be comfortable with people's lives and their future employment situation being dependent on results coming out of that system.

I think what we decided we had to do was to

develop a set of standards that we felt comfortable would withstand all of the ethical issues and very careful scrutiny and constitutional challenges and so on, and the scrutiny of the scientific community and the legal community.

So we didn't really look to see what was available out there. We knew what was available out there. We sort of sat down and tried to design what the ideal situation would be. I remember -- and Yale and I were talking earlier -- we thought that there would never be more than 25 to 50 labs in the country that could meet those standards, and Yale said more are rapidly getting there.

The fact of the matter is if you set standards,

and you set high goals, the community will meet those standards. I think that is what Sam was alluding to. I think within the on-site technologies, with saliva and so on and hair, if you set the standards, they will strive very hard to meet those or they are going to fall by the wayside.

I think that is the charge, Joe, that SAMHSA

really has to look to, is rather than be satisfied for what you are being offered, to set a set of standards that you will be comfortable with in the department, and all of the federal programs.

With regard to some of the on-site issues specifically, Mr Othman from Quest talked about the devices.

I think one of the reasons the devices were not discussed was we were specifically told not to get into any advertising. So the discussion was generic, and I am absolutely certain that all of the diagnostic manufacturers would be delighted to provide you with information, and probably even send a sales person to your lab to give you in depth briefings.

The training issue obviously is critical. The adulteration procedures, the various issues that were raised by Dr. Bost and Dr. Sample are important issues. I think again, if SAMHSA sets standards, the community will respond to those standards, and will do what you ask them to.

I think as the pressure was on us back in 1985,

the political pressure to develop a system, I think what is coming very soon is from the rest of America, and also within the regulated industries is a demand for a more efficient and cost effective system.

As I listened to John Mitchell yesterday going

through detailing the application for the process for the national laboratory certification program, almost every issue I recall there was an argument over major discussions and problems and deals cut and so on. Should it be plus or minus 20 percent, or is that too stringent? How about

10 percent? No, we can't do that. How about 25 percent? And so on.

I think some of the details there we have reached

a point where a lot of the early questions about accuracy and reliability, the issues of passive inhalation of marijuana smoke and so on led us to the decision to establish the program with the idea that it be skewed towards false negatives to assure that there would be a minimum amount of false positives in the system.

I think as Donna Smith said earlier, it is kind of fun to sit back at this point on the outside and realize that in general the system works, and we accomplished a lot in spite of the system, all the opposition to get it done.

So time's up.

DR. AUTRY: One serious comment, and then I will digress for a moment and tell you a little story. One of the charges to this board was to exactly what Michael said, and that is to outline the principles and establish the criteria that any testing technology must meet in order to be eligible for workplace testing. That will be part of the deliberations and the discussions that will be ongoing, and will hopefully come to some conclusions at the meeting in August.

I want to tell you a brief story. In my career I have taken over a number of my former mentors' jobs as I have gotten older; it's not necessarily that I have gotten smarter or better. When I took over the Division of External Research Programs at NIMH, one of my mentors gave me four numbered envelopes, one, two, three, four. He assured me that there would be times in my career in that job in which I would run into an insolvable problem, and at that point I was supposed to open the envelopes sequentially.

So the first time I ran into a major problem, I opened the envelope number one, and it said, blame your employees. The second time I got to point in my career where there was an insolvable problem I opened the envelope number two and it said, blame your mentor. The third time I got into a crisis, it said blame your boss. The fourth time I got into a crisis I opened the envelope and it said, make four envelopes.

Well, we are at the point where it is all Mike's fault.

MR. FORTNER: I've got a bit of Sam's problem,

because I don't recall an awful lot of questions being specifically addressed to sweat testing, but there were a few of them, so I'll try to make a couple of comments on some things raised this morning, and maybe references to some questions that have come up over the course of the last couple of days.

I guess I sort of endorse or reiterate some of the things that Dr. Selavka

mentioned this morning in terms of suggested roles. One of the questions that Col. Jacobs raised was what do we see the role for various technologies being? I think my general observation would be, or general suggestion would be is you review data and come to understand the nature of these technologies.

The properties of the technologies themselves will sometimes sort of naturally suggest the entry roles for the technology in the programs. I can think of some of the things I was talking about earlier. In the sweat testing I think there is a natural application for opiate investigations, because of the fact that this technology addresses the core question of heroin use versus other opiate uses.

Col. Jacobs specifically mentioned this morning

how he would think of our technologies relating to program changes like the opiate cut off issue. I think this gets right at it, and that change is certainly intended to focus urine testing more on heroin use. This is one way that you could do that in a more consistent fashion.

The sweat testing technique that we have been working with is really a monitoring technique if you think about it a bit. So applications in the workplace environment that involve monitoring would seem sort of natural candidates. One that was mentioned was return to work or rehabilitation testing.

We might think of sort of extended tour of duty, safety sensitive environments, oil rigs, that sort of thing as being areas where you might want to take advantage both

of monitoring properties of the device or technology like this, as well as deterrent characteristics.

It's actually something we didn't talk about much, but we do have some data that we'll be providing to you that suggests that a monitoring technology, as well as detection efficiency has some ability to deter drug use in and of itself.

I think there may be some applications for sweat analysis in cases where adulteration is suspected in urine testing. We have got some indications that this technique is pretty good, or at least differently sensitive to adulteration, so people being tested have to apply some different techniques. So as you look through the data, I think that sort of thing will come about, and we'll try to provide a little bit more information on that sort of thing in the future.

I guess I would sort of echo Sam's comment about

the automation capability of these technologies, and that there really is a lot out there that has not been developed for reasons that it has not been required at this point. If you think of common chemistry labs and the biotechnology industry, the techniques they are developing, they have

capabilities of doing enormous numbers of samples for very complex analytes at levels far lower than what we were concerned about.

There was a question raised about calibrations and controls. It is a very interesting one for all the matrices. It is an interesting one for urine as well. I think it is something we do have to take into account. We handle it a little bit different, and we provide a little bit more information on that.

I think there are definitely ways to do it. You either need to verify that there is no matrix effect, which you can do in your procedures, or you account for it. That data should be provided as part of any method validation that you would look at in terms of a method study or an SOP.

There were some comments or suggestions of

additional studies that might be made. I can think of one suggestion, a study of the effect of sweat rates and the efficiency of the clinical sensitivity of this technology within calimetric glove(?) might be interesting.

Dr. Huestis suggested a review of UCMS cut offs against existing screening cut offs. I think all of that stuff is good. It is a natural part of the technology's evolution, and once it begins to be applies, you don't stop the investigational work. There is actually quite a lot of that going on now. The application and the investigation kind of interactively develops it and moves it along.

One suggestion I might make for convenience and time's sake as well, sweat testing hasn't had the advantage yet of the conferences that have been available for hair testing, so you get together the practitioners and researchers in the field and swap notes, and develop the ideas to move forward.

There will be something like that this fall in Vancouver. There is a drug monitoring meeting being held. We will be assembling, at least in a workshop format, and awful lot of the people that have some experience here, and the information from that meeting might be very useful.

DR. AUTRY: Okay, anybody from laboratory urine testing want to comment?

DR. ST. CLAIRE: Actually, many of you may have noticed there were very, very few questions for urine drug testing, and I think that attributes to the fact that people very much understand what is happening in this particular arena.

That has been the result of some very strong programs, and I would like to just comment that I have been doing drugs for 20 years. I have seen an evolution from a lot of different perspectives of what regulations can really do. When I first sat on the committees to help develop laboratory standards, the expectation was we would have 50 laboratories that were going to be certified to do this testing.

After the first round of inspections and

proficiency testing, there were 10 laboratories, and it took a couple of years to get that number up to nearly 100. I don't think it ever got over 100. The number is kind of settling down in to probably 50. So it has taken about 10 years to get to the 50 labs.

One of the things I really want to play on is the idea of setting high standards. I was prompted -- I was thinking about this. I was kind of a fan of the "Forrest Gump" movie, but not the usual box of chocolates, but, "Momma always said, if you don't know where you are going, you are probably not going to get there."

I would like to just emphasize to the committee

the importance of setting goals and expectations, to be a little bit flexible in trying to develop those technologies, because as you know even within the federally mandated programs for urine testing, there has been some flexibility that has been allowed as different questions of interpretation, questions of -- we didn't know all the answers when we started this program.

It has been good to have a resource through some program documents and guidance of how to interpret things, and to provide the laboratories some flexibility in terms of reporting and interactions with clients and MROs and so on, but I think that that program taken that way has given the public sector a huge amount of confidence and credibility.

When we first started doing drug testing back in

the late seventies, early eighties, most of the challenges were to technology. We used to use GCs for doing TAC testing. We didn't have duderated internal standards.

After we were able to solve the problems and

questions of technology, the next thing that was challenged was chain of custody. Then we were able to develop very firm, very appropriate chain of custody guidelines and administrative ways to handle chain of custody problems.

Right now we are facing issues with the

collectors. As we do training for collectors and so on, that now becomes a diffused issue.

We also deal very significantly with these new

methodologies with respect to interpretation of some of the areas that are very much open to challenge, and trying to establish guidelines for what does the positive test really mean, and using the alternate technologies. I think that, not only for the alternative technologies, but will continue

to be a challenge in the urine testing programs also.

I think the main focus of the whole program is to decrease drug use. I don't think we should ever lose sight of the fact that this is not a punitive program, this is a very positive program. Through using positive mechanisms to getting people to substance abuse rehabilitation, to use programs that will be a positive in their life to really decrease drug use, because that is really the goal of the program.

I don't think we should lose sight of that with raising the standards and keeping high standards and high expectations, because that is where the program will be directed as those goals remain high.

So I thank you for that opportunity to make those

comments.

DR. AUTRY: Okay, I think we have covered the core areas. Anybody else before we start over again?

Let me suggest this. Do you want to just go in

the order we did it the first time? Anybody care? Somebody from the hair area.

DR. BAUMGARTNER: I just would like to make one final point concerning the controversy with the Navy. My two papers which were submitted, and which I believe will be handed out to the board, discuss the technical details in every nauseating nuance.

I would just like to respond to two very specific questions which were asked of hair analysis. One was why are we not doing wash kinetic measurements on carboxy THC? The issue is that there are some metabolites which are even better than large kinetics. The cocaethylene is one such metabolite.

Now the reason why we do wash kinetics with

cocaine of course is we only identify 50-80 percent positive cocaethylene samples. In other words, we have cocaine use, we have cocoa benzylethylene and cocaethylene, so then we use the wash in addition to, but it is the stronger criterion. Now carboxy THC is a similarly very strong criterion for use.

Now we do wash the hair, but to do MS-MS kinetic analysis would obviously be a very costly business. In safety net challenges we do even that.

There was a second question which deals with the apparent imprecision of recovery in assays. We should have included a third table, a third piece of data. What you see are the big statistical fluctuations are due to matrix effects. Let me explain what happens.

What we do is we take the test tube. We put the hair in and we spike into this test tube a certain quantity of drug close to the cut off level. Then we put this through the digestion process. Now we use the same hair. We digest it, and then spike into that -- the melanin is still there -- the amount we spiked in the first test tube, which we put through the digestion process. The idea is to see that we don't lose anything in the digestion process.

Now if you see the absolute values, you all see on top of it, because on day two and day three and day four we use different hair samples, so superimposed on that are the matrix effects. What we really worry about is the percentage loss. The percentage loss is of course the critical thing, and this is extremely tight. So we have 510 percent loss, and most of this we explain through very little binding to the melanin pellet. This is where we get our melanin data from.

Finally, I am tempted to speculate -- and this is only a theory -- why there were so few questions concerning urinalysis. Somehow I get reminded about the emperor, who may not have all the many clothes. Some people may feel that way, because we are all sort of going against the urine test.

I certainly have been blessed by criticism from

the urinalysis industry. Some people say some blessings are curses, but I don't believe it. I do believe in Preparian(?) philosophy, that criticism is the greatest act of friendship, and that you indeed improve through criticism. I have also had the opportunity of criticizing urinalysis, and I encourage everybody else to adopt the same view.

So thank you very much.

DR. AUTRY: Okay, saliva.

DR. ROHRIG: A point of clarification. When one

of the read comments was made, at least there was an implication that drug confirmations are not performed on all fluid samples. Those of you that were here the first day heard my presentation on GC/MS confirmation of cocaine at least for benzoylecegonine in all samples. That is a standard practice in the insurance industry.

A question from the board, a couple of them

pertain to what role or advantage would the oral fluid or saliva provide as compared to some of the other samples? One that immediately comes to mind is direct observation using a saliva collection device. You give it to the individual. He puts it in the mouth right in front of you; takes it out. You put it back into a container, seal it and begin the chain of custody.

So that is one role or advantage of oral fluid,

that unless you have a direct urine observation, which may not be socially acceptable in some arenas, it is an advantage.

Another question that was raised is correlation of saliva oral fluid cut offs to urine cut offs. I can only speak to cocaine, because that's the analyte that we have the most experience with, and this is empirical data. This is not based upon some of the nice studies Dr. Cone and his group have done in the dosing, but just in general population studies.

This involved several hundreds of thousands of

individuals, using the 10-20 nanogram per mil cut off we essentially achieved the same hit rate in the same population as one achieved with the 150 nanogram confirmation cut off for DE and urine.

There was a question about training. It is very important, and training is required for all fluid collection in the insurance industry.

Automation processes for screening are semiautomated, but the laboratories for doing production testing are putting hundreds of thousands of samples through the laboratory on an annual basis, and we have yet to reach the capacity of the laboratories as they exist today. So right now I do not feel that that is a burden or a challenge. We are doing it in production situations currently.

Lastly, there was a comment -- at least I hope I heard it wrong -- that the alternate fluids were against urine. No, and that's we call it alternative fluids. These are adjuncts or additional specimens that we can test for drug usage.

Thank you.

DR. AUTRY: Okay, on-site?

MR. EVANS: I have a question for Col. Jacobs.

You seem to be the board's Bubba detector. I have a 10 year old Dodge Ram pick-up truck. It is pretty beat up. I own a shot gun. I am a life member of the NRA. Do I qualify?

Now let me just say a couple of things that work against me. I'm a lawyer from New Jersey.

DR. JACOBS: Is the shot gun loaded?

MR. EVANS: Not right now.

In talking about Bubba, Bubba also can be a

victim. Bubba can be a victim of his own addition and his own drug use. I really love what Dr. Childs said. The question that I would have for the board is that looking at of these different technologies, are you doing

everything you can? Will these technologies help to detect Bubba's problem, and to deter Bubba's problem, and protect Bubba from killing himself or somebody else?

With on-site testing I think the answer is going

to be yes. I am a trial attorney. I have been watching the jury here, and every concern that you have can be addressed

by the development of proper policies and procedures. So I'm very relieved to be able to see that. We will supply you with how we think those policies and procedures should be developed, and you come back and tell us what you think.

Just a couple of little items I would like to

clean up. There seemed to be confusion about the DOT issue, and I guess I was not clear yesterday in what I said about that. A DOT employer can, under its own policies, not apply DOT sanctions, but under its own policies could do on-site testing and take some employment action based on a presumptive result.

Again, here I used to run the New Jersey Drunk

Driving Program. I have met a lot of victims of drunk drivers. The question always before in my mind was, was I doing everything I possible could to detect and deter and educate drunk drivers?

How would I explain to somebody that I was able to detect somebody's drug use before they stepped into that truck or drove that bus, and I took no action? At least to the extent of saying to the employee, look, you're not going to drive the bus today. I'm not going to take any adverse employee action against you, but I'm just taking you off line. Procedures can be set up so that an employee doesn't necessarily get singled out.

On the issue of employees who conduct the on-site tests knowing about the positive results, again, that is a procedural issue. With some employers, if they are large employers, it is not going to be a problem, because they are going to have a medical office. It might be someplace on the other side of the factory, in another building or another town where they test could be conducted.

You can use a local physician's office to conduct

an on-site test, a doctor who is just down the street. You can go and have that doctor do it. Again, there is not going to be that employment connection.

As far as training goes, we share your concern

about training. We certainly don't want our products used inappropriately. If you look at the on-site bills that we are sponsoring now around the

country, we emphasize training, certification. The Oregon bill is an example, where you have to register with the state department of health, supply certification that you are doing everything properly.

Forms is also an issue. We have developed a

number of forms which we will make available, an on-site negative test result form; an on-site positive result form; an on-site specimen collection chain of custody form. I think they could be very easily incorporated into existing DOT or HHS forms. I'm not sure if there would be any changes at all.

I again thank the board for their very kind invitation of inviting us to come here. We will get a lot of information to you. As far as how the tests work, there are a number of ways we can get that information to you. I would like guidance in how we can do that. We have videotapes we can send you. I can just tell all the manufacturers to send the stuff to your offices, and no sales people will call, I promise.

The videotapes I think are a real way of doing

that. If you will give me guidance, we will supply you with information and examples of all the tests and show you how they work.

Thank you.

DR. AUTRY: Okay, sweat?

MR. FORTNER: Good morning. Just to follow-up

with some of the questions that Bob didn't answer, that are

addressed by the board. Aaron, with respect to how does it fit into the program, I think there are a number of issues that have been addressed in there.

Certainly one of the advantages that the sweat

test does is it gives a little bit different time window. The one criticism I think we could all agree upon on urine testing, whether it is on-site, or whether it is centralized testing is it represents a relatively narrow snapshot in time.

If you look at the mechanisms that are widely used right now to circumvent the drug testing programs, internal adulteration, excessive hydration is probably the most common approach that is used, and certainly would be inherent in any of the urine testing program. The advantage that you have with somebody who excessively hydrates is you corresponding produce significantly more sweat, which then can become relatively self-defeating to the drug abuser.

With respect to establishment of cut offs or how

do those things reflect, I have had some interesting conversations over the past few days, and not to criticize the urine program, because it certain operates extremely well using the established cut offs. The cut offs used in the sweat testing program though, I think if you will recall the data presented over the last couple of days as more empirically determining using RFC curves.

We have had some interesting discussions with

individuals in terms of what would happen if we went back and did RFC curves now, applicable to the urine testing? Certainly it might provide some insight in terms of whether those cut offs are appropriate, or how they might be applied.

The other issue with respect I think to matrices effects, certainly the approach that is most desirable in forensic toxicology is to use the same matrix to accomplish variances in extraction efficiency as you may see. In our experience in spiking directly on to a worn patch is that you do introduce those matrices.

So if your recovery is less than 100 percent,

which is will be off of a patch, at least that bias is introduced uniformly across. Your standards, controls and calibrators are subject to the same analytical conditions that your patient samples would be.

With respect to some questions on proficiency

setting, certainly that does currently not exist. This technology, the analytical aspect is not proprietary. There are several other laboratories in the U.S. and in Europe who are involved in sweat testing. Certainly the Center for Human Toxicology is one of them, as they participate in some NIDA sponsored research programs.

So that intralaboratory comparison availability is certainly there, and as a coordinator of sweat, we would certainly put some of that information together and provide it to the board for review and consideration.

Thank you.

DR. AUTRY: Okay, laboratory urine testing?

DR. ISENSCHMID: One of the things that was

mentioned several times at this meeting is perhaps urine drug testing is not getting its share of criticism at this meeting, and perhaps that is true. I would like to suggest that perhaps criticism of urine drug testing is why are having this meeting.

I think we have seen a lot of changes occur in

urine drug testing. We have seen proposed changes of cut offs. We have

seen some cut offs changed, some that were discussed that haven't been changed, and some future ones that may occur as a result of a lot of good, scientific data

that has been obtained over the years in urine drug testing. I think urine drug testing has a certain place,

and I think a lot of these other proposed technologies provide some exciting adjunct information that can further provide very useful data in drug testing prevention, and look at some different time windows.

So I would encourage that data also be provided

for these alternative technologies. The more data that can be made available, the more readily one can interpret how it might be used in future program issues, and I look forward to learning more about it.

DR. AUTRY: Dr. Sachs, you wanted to make a

comment earlier?

DR. SACHS: First, a comment to Dr. Blank's

speech. We also received a letter from a student from a police academy, but concerning a urinalysis; a positive test for urinalysis. That was a very experience laboratory. It was the laboratory that published the first procedure of detecting MUM(?) in urine, and it was published in the GAT.

Just what I wanted to say is that it is of no use

to take one single letter to discriminate against one alternate methodology. We make mistakes in urine labs and in hair labs.

He also mentioned the name of Dr. Kidwell, and

that leads me unavoidably to the hair consensus of Genoa. This is published the Forensic Science International this year in the first issue. It makes just general recommendations at first about hair, collecting, how standard hair analysis should be performed, and decontamination procedures, and some recommendations about the determination of the metabolites that are necessary to detect some metabolites, and some recommendations about metabolites to parent drug ratios.

It ends that we recommend that hair testing is acceptable for forensic applications if the chain of custody is maintained, if external contamination is considered, if a proper definition of a positive result is established, if performed in a qualified laboratory, with accepted methodology, and if the laboratory participates in external proficiency tests.

Now if that is for use for workplace testing, if there are too many ifs, then it is your decision to use it or not to use it. To clarify what I

said yesterday, in Germany nobody is thrown out of his job because of positive hair tests. Nobody is also not thrown out of his job because of a positive urine test.

Thank you.

DR. AUTRY: Thank you. Saliva, any additional

comments or concerns?

PARTICIPANT: Don't beg.

DR. AUTRY: How about on-site? Additional

comments or concerns? Sweat?

DR. ARMBRUSTER: I can hardly resist the change to talk a little bit more about sweat, because we're really excited. I think it does have a lot of potential. I will try to get sharp though.

Sweat testing as we have really first utilized it has been our criminal justice part of the laboratory operations. PharmChem does a lot of criminal justice work, in other words with probation and things like that. So I don't need to describe how it has a logical connection if you are trying to monitor people that are on probation, the treatment is separate.

So we have really been using it in that arena.

Who our clients are, that's not my bailiwick, so I don't know how many workplace type clients we really have at this

time, if we have any. We may or may not, but as Bob Fogerson said, certainly there are some potential uses of sweat testing in a workplace scenario.

I think that we never intended to create sweat

testing as a replacement for urine testing, but again, as an adjunct to it. I think that our attitude is that we are here to help. In other words, to flesh out the total picture of what goes on with people who have drug problems with sweat testing, and to work in conjunction with urine, with hair, with saliva and any other fluid or alternate specimen that we could possibly take advantage of.

So the question I think is how we can best interprelate with these other sources of specimens and give you a better handle on how to deal with the drug problem in the country.

Technology -- I think we feel comfortable with our GC/MS procedures right now. We presented that data. That is not to say that with experience we are not going to modify it as necessary, and we probably will.

Screening -- it's FDA approved and so forth. I think we could probably do a better job, and I don't think we are totally content with where we are at with screening.

As far as automation, Dr. Niedbala already

indicated that the microtider will format; does lend itself to some automation. I think it is really semi-automated. I look forward to the day when it can be more fully automated with bar code reading and just load up reagents and keep pushing specimens through in a more fully automated system such as we have with urine testing.

Again, recognize that we had to go out and kind of ask manufacturers to work with us, and nobody necessarily wanted to jump on the bandwagon and take a chance from the very beginning with only a limited market there.

Calibration controls -- Dr. St. Claire has

described how we spike that and so on and so forth, and still we're in a learning curve here. It is the infancy of sweat testing. I thought maybe we should make instead of synthetic urine, how about synthetic sweat? We could probably analyze what's in sweat and come up with a reasonable approximation, and that's something I get kind of excited about exploring down the road.

Lactic acid is something that at one time we were using as a marker, just as we used specific pH as a marker in urine testing. We may go back to that; we may find something better than lactic acid. I said to Dr. Peat the other day, why don't you use salivary amylase as a marker, instead of IGA. He said, it has been done.

It has been used. It's a good idea. It's

cheaper, probably easier, except it turns out that animals produce salivary amylase as well, so how do you know it's not as a rover specimen instead of a real one. It turns out that the antibody for IGA is specific for human IGA. So these are things that you learn as you go along, and we look forward to having that opportunity.

One of the board members said we have to remember we're not here to detect the last nanogram, picogram, fentagram. So I think we want to approach sweat testing, and maybe not go too far off the deep end technologically. I think maybe it's important that we do a good, solid, forensically defensible job that these results are going to stand up in court, yes, but how far do we want to go?

I think it would be nice if we could keep the technology within the reach of the typical laboratory, the typical practitioner in the field, so it doesn't become so arcane and just so involved that we are limiting ourselves to just a few specialists or specialized laboratories that

can do it.

Finally, at PharmChem we are kind of unique,

because we are sort of the only game in town right now. How long is that going to last? I have no idea. It is kind of an advantage and disadvantage. We like to have this monopoly. You have to come to us if you want to do sweat testing, but on the other hand we are missing out.

The advantage is we don't have some of the -- as I kind of feel -- disarray as with hair testing. In the future we don't talk about sweat testing, we talk about sutorferous fluid.

DR. AUTRY: Any comments from laboratory urine

testing?

I know that Dr. Baumgartner has a lot more that he would like to say, but I'm going to ask that instead of prolonging the discussion at this point, that we do a couple of things. One is that you have already heard that we want to have any additional information for the record that would help bolster alternative technologies or answer any questions that have been raised, and we would certainly like to have that.

We also would like to ask if we can lean on our coordinators one more time, and ask that you provide us some very specific information. If you have heard key points that you think need to be addressed or that need additional data, please talk with the people in your field, and I mean all the people in your field that you know to try and get that data, and to present it to us.

There are some specific areas that the board has identified that they would like to have information on, and Donna is going to talk a bit about that.

DR. BUSH: Thanks. For the record, I know that

Dr. Autry in his opening remarks mentioned who the coordinators were for each of alternative matrices and whatever technologies were represented. So I would like to reiterate that so that at this point in time we have all gotten comfortable with each other, and we know sort of who the point people are on things.

So Dr. Don Kippenberger was the point person on hair. He has nodded in agreement. He has let us know that he would get us, meaning me for the board or Joe Autry for the board, the consensus of the Society of Hair Testing report concerning what we have heard from Dr. Sachs and in the presentations, because we need that. I know they want that.

Also concerning hair, the board passed some

questions to him concerning baldness and chemotherapy issues. So Don.

Sam Niedbala was the point person on saliva. Specific requests here, dry

mouth, artificial spit. I guess that is different, artificial spit versus artificial oral fluid. I understand now they are very different.

DR. JONES: There is a commercial product so

named.

DR. BUSH: There is a commercial product so named?

Artificial spit.

Also, I believe during Dr. Rohrig's presentation

he mentioned in his lab there are like five devices that are tested, used, whatever. Can you help compile some of that?

DR. ROHRIG: The names of the devices?

DR. BUSH: The names of the devices. Some of the characteristics, descriptions. Are the same types of testing procedures, analytes of interest used for each one of those? You know where we are going with this, right? Thank you.

Neil Fortner was the point person on sweat. Neil,

particularly there was a question here about cold weather. In other words, reduced perspiration generation.

DR. JONES: Could I ask one other question there?

Neil, you made reference to increased sweat production on hydration. Could you also make a reference to that for us, or give us that information? I'm just not familiar with that particular bit of data.

DR. BUSH: David Evans was the point person on onsite drug testing. A particular item that the board would like information on is shy bladder. How do you deal with shy bladder in that situation?

The lab and mandatory guidelines-based testing point person was Dr. Walt Vogel from our office. So should there be any information to come to the board, you can call him whether you want, or what the volunteer of information should need.

Could each of the alternate technologies address the issue of sample unavailability. I guess the hair, the sweat, the saliva, urine on-site with the shy bladder. Please add to the unavailable specimen question their

definition of an unsuitable specimen at the collection site.

So there are specifics, and point people please write that down.

May I ask that information that each and every one of you wish to contribute and get to the board come through Dr. Autry as director of this board, as chair of this board, or me, as executive secretary of this board.

Our mailing address, should you not know it:

Dr. Joseph Autry or Dr. Donna Bush at the Division of Workplace Programs, CSAP, abbreviation for Center for Substance Abuse Prevention, SAMHSA, our parent organization.

The street address is 5600 Fishers Lane, Room 13A-54, Rockville, Maryland, 20857. You can also get that from Federal Register notices, and it is in the book.

We have a list of observers that we have compiled.

It is available at the door as you exit in the back. There

are 184 of you observers who have chosen to join us here. We are grateful for your attendance, your comments, all of that.

Additionally, we've got members of the board and

the requested presenters and moderators. All told, we have over 225 people attending and presenting at this meeting. This is great. We never thought it would be this way, or we probably would have approached our Federal Register notice a little differently, because we got an awful lot of calls, how do we register for it. We didn't even know. We never thought, we had never had this many people at a board meeting before.

This list that has been generated, we are going to use this to generate any mailing list. Many have left, so we are going to have to send out a mailer concerning the availability of the court transcript of this meeting. Now you all have the slide handouts. They would be very difficult to get up on our Web site.

So what we are going to do is make the court transcript available through the Web site, as well as also hard copies at some time in the future, but what you might want to do is jot down this Web site address so that you can use it. We have got our lab list up there. We have got our collection site manual up there. We have got other things you will be interested in up there. The address is: www.health.org/workpl.htm.

Now we have been made aware that we will not get

the court transcript for 10 working days after today, so don't go home and check tonight; it won't be there.

Dr. Autry made reference to a meeting of the board

to follow this one to continue this discussion in August. We have

coordinated schedules with the members of the Drug Testing Advisory Board, and it will be August 5 and 6. That will be a Tuesday-Wednesday, and it will be in this same place.

Today is the 30th of April. When we have made requests for submission of items from the presenters or from the public to go through me or Dr. Autry, we will pass them onto the board. We need them three weeks from today, please. We've got a big job ahead of us. We need to give the board the time they will need to take into account all the items they will need to consider. Is that May 20th? Someone tells me that day is May 20 for us to get items from you.

I go back to the Star Trek movies and the Star

Trek series, of which I am a real fan. I'll tell you what, all the commanders have always had a really great Number One. Well that is Number One here. Dr. Walt Vogel is our Rieker and Spock. He is so logical and he is so organized, always picking up after us.

So Number One wants good hard copies of all the slides please, for us to be able to make a real quality document when we go to press with this. So if we don't already have them from you, please send them to us, me or Walt. I personally prefer Power Point 4.0, 7.0 whatever you have, but I will take what I can get.

DR. AUTRY: Having heard the lunch alarm go off a few minutes ago, and have seeded our time beyond that, I'm going to suggest that we break for lunch, come back at 1:15 p.m.

At that point I want to do two things. One, I

want to give the board a chance to discuss among itself any issues or questions or comments that are still outstanding, having heard some of the responses that we go this morning.

Then I am going to do something that I probably

ought to know better than to do, but I'm going to do it anyway. That is, I want to set aside a few minutes at the very end of the meeting to let you tell us how we can do this better, because we are probably going to do this again.

If there are things that have worked particularly

well, we would like to hear about it, but I more want to hear about are there any complaints or things that we should have done differently, so that we can weave that into what we do the next time.

With that, we'll break for lunch. See you back

here at 1:15 p.m.

[Whereupon the meeting was recessed for lunch at 11:59 a.m., to reconvene at 1:15 p.m.]

A F T E R N O O N S E S S I O N (1:20 p.m.) DR. AUTRY: What I thought we might do this

afternoon is to give anybody who is here in the audience, who hasn't had a chance to make a comment or to respond to some of the questions that were raised, to take the opportunity to do that. I know that a number of the moderators and some of the presenters from the past couple of days may have additional comments they want to make. So if you have individual comments or criticisms or concerns, I'm going to let you put those on the table, on the floor right now.

Then I want the board to raise any last issues

that it has, recognizing that they have a lot of information that they are still hoping to get sent into them. I'm going to do a brief debriefing and say what could we have done differently? What could we have done better?

So if there are any commenters or questioners or

people who feel like they need to say something or want to say something, but haven't had the opportunity to do that, now is your chance. I'll ask you to just keep it brief.

DR. SUN: I'm Kenneth Sun. I'm from Methodist

Hospital in Indiana.

I just want to take this opportunity to thank the board for inviting us. This has been a very exciting and enlightening discussion.

Since we are in Washington, I just have a very

simple, humble statement to make. That is, in politics what is not said is what counts, and what is said does not count.

In science usually what is presented is fantastic. What is not presented is incredible.

Thank you.

DR. AUTRY: I am reminded of Will Roger's statement that there are two things you ought never watch being made. One is policy and the other is sausage.

Further comments?

DR. HUESTIS: I have really enjoyed the meeting and have learned some different things here too. One I

would like to point out is saliva. What hasn't been brought up I think is that we have tended to think of saliva as having a close detection window as blood. The fact that you are measuring parent drugs in these two fluids, a lot of work has been relating saliva to possible impairment. That is one particular application with saliva, is that it might be related closer to blood impairment.

I have learned here today that you can get the

detection limits down, and look at the analytes like benzodiazepines and to try and come up with windows that are not windows, but detection rates that are similar to urine.

I think it is tremendous to try and put out

guidelines and set standards for these alternative fluids that will insure the reliability of the testing, and protect the confidentiality of individuals.

I think the beauty of alternative matrices is the fact that they do offer different windows of detection. What we ought not be doing is to try and force them into giving us the same kind of information that urine does, but to appreciate their strengths and the different kind of information they can provide us.

So I'm a little surprised at trying to relate it

all to the window or the detection rates of urine. I think we should look at it differently to see how they can be applied, and the type of information we can learn from them.

DR. AUTRY: Thank you. I think that is also a

point that Dr. Selavka made both in his presentation and also this morning.

Let me read one question or comment into the record. This is from Irving Sunshine, who had to leave. What questions are drug testing programs trying to answer? One, did the person involved use a drug of abuse in the recent past, or two, is the person involved a drug abuser whose habit of abuse will harm society? When the question is stated, then one can discuss which technology is relevant.

Other comments or questions?

DR. MANNO: I just wanted to say that I feel that there is some cautious urgency about deciding to do, what alternative to testing. In my position I have a lot of opportunity to interact with a lot of different groups, and I am hearing the same message from all of them, from

employers, from administrative law judges and workmen's comp cases, from plaintiff attorneys, from prosecutors, from defense attorneys, we like

urine drug testing.

It's very functional. It gives us a lot of

information, but we want more information than we can get from urine. We want to know performance relevance. We want to know how often or how long a person is using the drug. We want a lot of diagnostic and clinical information that can only be provided by alternative testing.

The other thing that I notice is that the number

of true experts, people that are working or doing research with sweat and hair is very limited. I would propose that these small groups get together, take the urine guidelines and erase urine and fill them in as you feel they should be appropriate for your particular field.

Then summarize what you can trust, what you can't trust, and what needs more research. Make it not an official document, but make it clear to the rest of us that know enough to be an expert at home, but not an expert in the broad sense of the scientific community.

I think by doing that you can move a little more quickly, but not lose caution and care, because we have to do this right. If it is not done right, it is going to screw it up for everybody.

Thank you.

DR. AUTRY: Thank you. Other comments, questions? DR. CONE: I've probably said enough over the past

few days, so I'll make my comments brief. I am an advocate of valid drug testing of any matrix, because I think going back to Marilyn's statement and all of our statements, we understand that we can get more information the more testing we do, and the different kinds of matrices will give us additional information. The word "valid" I think is useful in the context that I have used it in. Does the assay accurately detect human drug use?

In terms of validity, I think it is important that we understand that science evolves, our understanding of processes evolve, and that it is an ongoing process. We can't say that with the perfect test. Urine certainly was not perfect; it is not perfect now when it was implemented.

We still have to go back to basic definitions.

Does the test do what it is designed to do? To some extent I think the DTAB board needs to assess the state of affairs, but it is not their responsibility to validate assays. It is the creators' responsibility and it is the users' responsibility to validate those assays and present the data for honest, open evaluation as we have seen in this meeting, which is a wonderful example of democracy in science in action at the same time.

It is stressful. You see some warts every once in

a while, but the overall process comes out looking pretty good in my estimation.

So I'm very pleased to have been a part of this process, and I applaud Dr. Autry and his colleagues for allowing this to occur, and I hope to see a lot more of it.

I just want to note from the board though, what is wrong with fingernails and ear wax and sebum and all of those other good things?

With that, I'll close and say thanks to all.

DR. JONES: You forgot tears and a few others there too -- sneezes.

DR. AUTRY: All of you have to remember one of

Ed's opening slides, which said there is scarcely a part of the body that cannot be examined for profit -- or was it with profit? I can't remember, Ed.

Other comments? Okay, let me turn to the board

and give you guys and gals one last chance of raising the issues or concerns. I know you have asked for a lot of additional information. We have had our board coordinators take on responsibility of getting that too. We have also

had everybody in the audience have the opportunity of providing whatever additional information would be helpful to the board.

So you may have asked for everything you need and more. You may not have more to ask for, but I'll give you a chance anyway.

DR. PINDER: I believe that from different people

in different ways we have heard of how the alternative samples could best be used. I would like if you would submit to us your opinions as to how each alternative specimen can best be applied, so we can clearly look at what your opinion is with regard to how you would apply testing of sweat, or how you would apply testing of ear wax or whatever.

DR. AUTRY: I might add to that, one thing that might be helpful to the board is when articles or additional information come in, if you could identify either in a cover note on the margin what section or what issue this seems to address from your perspective, it will make it a lot easier as we are plowing through the pages and pages and pages of paper if we know hey, yes, this goes with the section on internal quality control or on interpreting or whatever, or on both, whatever it happens to be.

DR. JONES: If there are no questions, I would

like to make one statement. May I, sir?

I certainly want to echo some of the Ed's

comments. As a board member and as an individual I want to thank Dr. Autry's staff for putting this together. I think we have seen an assemblage of a variety of individuals that are in all the whole area of testing for drugs of abuse come together in a fantastic forum.

We have had the hair testing conferences. We

heard that we are going to have a therapeutic drug monitoring sweat testing conference coming up. The hair testing has been hair testing people. This conference coming up potentially is going to be only the sweat testing.

We have had the urine testing conferences.

Here we have put together and merged all of these disciplines together, and started a dialogue amongst ourselves that I think can only be beneficial for the whole program. You and your office are to be commended, and I as a board member say that, and I as a individual say that, and we thank you.

DR. AUTRY: Let me make one comment, and then I

will give everybody a chance to tell us what you would like to see us do better next time or what we did wrong this time, because I do see this as a beginning process of what will probably happen on a periodic basis. Maybe we will get to the nails and sebum and the semen and everything else that you have sampled over the years, Ed.

Certainly we want to see this process continue

where we do look at whatever is out there, and look at it across the board, and not limit it to one area. We heard somebody this morning talk about looking at non-biological measures or non-chemical measures. That is something that I think also will be looked at by the board over time. There is no reason why this has to be limited just to in chemical measures.

This is the first time in my tenure with the board that we have ever had a meeting that has been entirely open.

The only reason we close meetings when we do meet is when there is proprietary information that we are discussing that might pose harm to one of the laboratories or to some segment of American society. We don't close meetings for anything other than proprietary information.

The only time this board has met at this meeting

that has not been in this room has been when we were talking logistics like what to do with this morning's table arrangement, or to schedule a time for the next meeting.

On the first night we met with all the presenters, just to lay out the format in what we expected for all of them to do. Other than that, you have seen this board every time that they have been together this whole meeting. I think from my perspective, to have that kind of openness, we are out here, so whatever is being said, whatever is being discussed has been a real plus.

I personally have benefitted from it tremendously because of the interaction and dialogue that we have had with all of you, and that you have had with each other. So I think that has been very good. Certainly the meeting that we have in August will follow the same format.

We will also allow time then, as we have now, for public comment, because we do think that that is important.

I am reminded of one of the notes we got this morning, that

it is also important to have the employers or the end users be a part of this process, because they can tell us how this really impacts them.

Donna Smith made fun this morning of what it is

like now having lived by the regulations she wrote. Well, I think it is important to hear how those regulations do affect people, and how it is implemented in real life, not just what we put down on paper, because those problems come back and they need to be dealt with in order to make whatever program is here more effective.

So having said that, let me open the mike to what could we do better, what did you not like, what could we do different about this type of meeting?

DR. MANNO: I thought the format was excellent.

The only thing that I would suggest that you consider is that the groups that make the presentation, each evening Monday and Tuesday of the same format, get together and discuss the relevant issues, and then as a group, with a designated leader on the third day, present those issues. Present the hair issues -- what you all agree, what you disagree and what you need more research in.

That will help clarify for the ignorance of those

of us who don't work in an area, exactly where you are. Go to a nonsmoke filled room together, with your own expertise and work it out and come to some understanding. Present as part of the third day.

DR. AUTRY: So asking the coordinators and the

panelists with relation to an individual area or an individual technology to try and get a consensus among themselves and bring it back to the group; or non-consensus.

Other comments, questions?

DR. BOST: Much as Skip has noted just a moment

ago, this conference has been different than earlier conferences. The previous ones were devoted specifically to discussion of hair and the information that we knew about that. This one has included alternative matrices in much the same time frame, i.e., a day and a half or two days.

Because of the additional specimens, the amount of

information about each has to be somewhat limited to fit within the time frame. I think that there is information that would have been nice to have, but because of time constraints we simply can't get it all in, and I understand that.

I would suggest that for August we have already

had the basic introductory meeting now. Let's go beyond that and get to some of the more detailed information that is available, and can help us to refine some of our opinions, to make some of the specific decisions that are

ahead of us.

DR. AUTRY: That is a point well taken. I think getting into some of the very nitty-gritty issues, and maybe looking at differences of opinion that are in press or are in print, and looking behind sort of the overview course that we have had today is going to be necessary. We hope that is some of the material that will come in to help the board in getting ready for the August meeting.

What else can we do differently or do better?

DR. WU: My name is Tony Wu from Brown Deer,

Wisconsin, where the potassium nitrate was generated I was told.

I truly enjoyed this meeting, and also this is the first time that as far as I am aware of with the drug testing for a long time, this is the group talking about different issues.

Now as the different matrices of the door walked into the potential workplace drug testing, and I would to know perhaps from this group, or probably specifically from you Dr. Autry what is the procedure involved from this point on in order to make these types of tests become an accepted legal being? What is the time involved? What are the steps? This is the first step as I understood it, and then the next step is what?

The reason that we need to know that is because those of you that are in certified laboratories certainly will be very much impacted financially by this type of testing, and perhaps many of us in the certified laboratories

will be closed down as a result of the on-site drug testing.

I think it is perhaps for particularly those of

you in the policymaking positions should let those of us who have spent lots of money to get our laboratories set up and to do these types of testing, certainly you owe us to let us know what is forthcoming, so at least we are prepared accordingly.

I realize you guys are not going to approve as of tomorrow, but we would like to know this process involved.

Thank you.

DR. AUTRY: Let me talk a little bit about the

process. As you heard, I think it was Donna Bush or Donna Smith this morning that said the government does not move fast, and that is certainly going to be true in this area, just because of the logistics that you have to go through when you have rulemaking.

What we hope to do in August is to have the board come back and do essentially three things. One is to review the principles and criteria, and see if those are the appropriate standards that any kind of drug testing needs to meet.

The second is to review the existing technologies and specimens that are available, and determine where their strengths and weaknesses are, and in what areas do they meet those criteria, and in what areas do they still have improvement. In the areas where they need to be improved, what can be done to help them come up to meet those criteria?

That is what we hope to accomplish in the meeting

in August. Now that may be a bit ambitious, and I am well aware of that, but it will be another step in that process.

What will happen at some point, whether it is then

or at some point down the road is that there will undoubtedly be a recommendation for inclusion of some of these technologies or specimens in the federal workplace program. If the board makes that recommendation, HHS has to decide whether or not to accept the recommendation. If they

do, what is going to be necessary to implement that kind of program?

We will then have to publish what is called a notice of proposed rulemaking or NPRM, which is telling the public what we are proposing, give them a period of time to

comment, get the comments back in, analyze, respond to those comments, and then go out with a final rulemaking.

For us that is probably going to take probably

close to six months if I am really optimistic and don't listen to history, or more likely it is going to take at least 12-18 months, and probably closer to the 18 months if I do listen to history. If it turns out to be a particularly controversial area like my colleagues at DOT and NRC have to deal with, it can deal anywhere from 2-4 years, but that's the process.

DR. WU: [Question off mike.]

DR. AUTRY: That will be part of the comments.

That will have to be weighed in, in HHS's decision. I can assure you that our Office of General Counsel will consult with the Department of Justice just like we did at the inception of this program. We will also consult with the Office of National Drug Control Policy to answer many of these very questions.

We don't take rulemaking or guideline making very lightly. All of these issues have to be addressed before you can change a policy. If we were to go out with a policy and a notice of proposed rulemaking, we would lay out what had been done in answering those kind of questions in advance. To the extent that we miss them, I can assure you somebody is going to write in during the comment period and put them on the record for us to respond to.

What else would you like to see different? What

did we do wrong this time? Come on, we couldn't have gotten it better. I have been in the bureaucracy too long. What's the hand comment? Got you -- the room issue. Good point.

Again, part of the logistics discussion my staff

and I have had, when we put this meeting together I think we underestimated the interest in the forensic and scientific community in terms of this meeting. We did not plan to have advance registration. I can assure you for the August meeting there will be advance registration, and we have already booked the entire ballroom.

What happened was this room was booked. We didn't think it would exceed the size of the room, and then as more and more queries came in, it became very clear we would. The other ballrooms had already been booked, so we couldn't add them on. Of course the hotel is very reluctant to move somebody into another room.

For the August meeting we have expandable space,

and we can contract it based on how many people we have in advance registration. So yes, we thought that one through.

Thank you.

Anything else? I don't want to read myself in The Washington Post as Autry gets this wrong. We have a running joke my family. My son, who is now 23 and I have had this going since he was about 16. He says, "Well, Dad, you didn't make The Post this morning. You're doing pretty good."

Other comments from the board?

I want to thank all of you. From my perspective -

- this is not denigrate the board -- it is really you who have made this meeting happen. I especially want to thank the coordinators for the work that they put in getting appropriate representatives from their industries and areas to come and present and be a part of this process.

I think that is a process we will continue,

because I think you know the people in your fields better than we do, and it is up to you to be their representative, their spokesman, and to bring their knowledge to us. To the extent that that has worked well, and I think it has, we will continue that process.

Thank you. We appreciate your attendance. We appreciate your input, and we look forward to seeing you in August. You will be getting notices.

[Whereupon the meeting was recessed at 1:50 p.m.]